Exhibit A

Designation Run Report

Altonaga 10-22-13 Jones Trial Depo Designations V4

Altonaga, Bill 10-22-2013

Plaintiffs Designations 00:11:34

Defense Designations 00:06:02

P & D Designations 00:00:04

Total Time 00:17:40

Page/Line	Source	ID
7:15 - 8:4	**Altonaga, Bill 10-22-2013 (00:00:48)** 7:15 Q. All right. It's my understanding that you are 7:16 a medical doctor, certainly, by education? 7:17 A. Correct. 7:18 Q. And if you would, highlight your educational 7:19 background for us. 7:20 A. Okay. I went to college here in Miami, and 7:21 then I went to CETEC University in the Dominican 7:22 Republic where I got my medical degree. Subsequent to 7:23 that, I went back and got my second doctorate in 7:24 optometry in Boston at the New England College of 8:1 Optometry, practiced primarily as a clinical optometrist 8:2 for 19 years. And like in 2005, I believe, I took a 8:3 career change, and I started working for Alcon 8:4 Laboratories in the medical industry.	05_14_18 Combo Jones trial V4.1
8:11 - 8:16	**Altonaga, Bill 10-22-2013 (00:00:16)** 8:11 Q. Do you have what we typically know 8:12 about here in the States as a four-year bachelor's 8:13 degree or a four-year degree at all? 8:14 A. No, sir, it's not a four-year degree. It's 8:15 undergraduate courses that allowed me to enter the 8:16 program that they had in the Dominican Republic.	05_14_18 Combo Jones trial V4.2
14:4 - 14:9	**Altonaga, Bill 10-22-2013 (00:00:15)** 14:4 Q. All right. And just so we all understand one 14:5 another, while you have a medical doctor degree from 14:6 CETEC in the Dominican Republic, you are not a licensed 14:7 medical doctor in Florida or the United States; is that 14:8 correct? 14:9 A. That is correct.	05_14_18 Combo Jones trial V4.3
33:17 - 34:10	**Altonaga, Bill 10-22-2013 (00:00:49)** 33:17 Q. And what is the underlying purpose behind 33:18 postmarket surveillance? 33:19 A. To gather document information, to investigate 33:20 the event that has occurred, or alleged to have 33:21 occurred, and determine the root cause of the problem, 33:22 and, if necessary, implement changes to try to mitigate 33:23 it from happening again. 33:24 Q. All right. And is there an ultimate safety 34:1 purpose behind that postmarket surveillance concept? 34:2 A. Sure.	05_14_18 Combo Jones trial V4.4

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	34:3 Q. What is that ultimate safety purpose? 34:4 A. To assure that the devices are as safe as they 34:5 possibly can be. 34:6 Q. What about from the standpoint of the public, 34:7 what is the underlying safety purpose behind postmarket 34:8 surveillance? 34:9 A. To make sure that the manufacturers are aware 34:10 of things that could harm people.	
71:24 - 72:7	**Altonaga, Bill 10-22-2013 (00:00:23)** 71:24 Q. All right. Are you familiar with the term 72:1 "misbranding"? 72:2 A. I am. 72:3 Q. What is it? 72:4 A. Misbranding means that you can mislead or 72:5 provide information that is false or misleading. 72:6 Q. All right. And give me an example of 72:7 misbranding.	05_14_18 Combo Jones trial V4.5
72:11 - 73:23	**Altonaga, Bill 10-22-2013 (00:01:35)** 72:11 Q. In the context of promotional materials, does 72:12 misbranding apply to those types of materials, the 72:13 concept? 72:14 A. Yes, it could. 72:15 Q. Does misbranding apply to posters? 72:16 A. Yes, it could. 72:17 Q. Does it apply to tags? 72:18 A. Yes, it could. 72:19 Q. Does it apply to pamphlets? 72:20 A. Yes, it could. 72:21 Q. Circulars? 72:22 A. Yes, it could. 72:23 Q. Booklets? 72:24 A. Yes, it could. 73:1 Q. Brochures? 73:2 A. Yes, it could. 73:3 Q. Instruction books? 73:4 A. Yes, it could. 73:5 Q. Direction sheets? 73:6 A. Yes, it could. 73:7 Q. Information on a manufacturer's website? 73:8 A. Yes, it could.	05_14_18 Combo Jones trial V4.6

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	73:9 Q. Okay. So if, for example, Bard, in any one of 73:10 those mediums, said that the failure rate, for example, 73:11 for migration of the Recovery filter is similar to 73:12 competitor filters and that wasn't true, would that be 73:13 an example of misbranding? 73:14 A. It could be. 73:15 Q. Could be or would be? 73:16 A. The way you posed the question, if it were 73:17 untrue? 73:18 Q. If it was false or misleading. 73:19 A. If it's unsubstantiated, then it would be false 73:20 or misleading. 73:21 Q. Well, when you say unsubstantiated -- 73:22 A. Meaning you don't have the facts to support 73:23 that particular claim.	
86:2 - 86:10	**Altonaga, Bill 10-22-2013 (00:00:27)** 86:2 Q. Do you agree that the performance failures of 86:3 marketed medical devices can pose serious risks to 86:4 public health? 86:5 A. Yes. 86:6 Q. Do you agree that recalls serve both to correct 86:7 defects in current and future devices and to notify 86:8 users of potential risks and steps to minimize the 86:9 impact of failure -- of device failure or malfunction? 86:10 A. Yes.	05_14_18 Combo Jones trial V4.7
87:2 - 87:4	**Altonaga, Bill 10-22-2013 (00:00:07)** 87:2 Q. Well, I mean, I'm asking you your 87:3 understanding. Would that include a medical device that 87:4 fails to perform as intended?	05_14_18 Combo Jones trial V4.8
87:6 - 87:6	**Altonaga, Bill 10-22-2013 (00:00:02)** 87:6 A. I would think that that is possible, yes.	05_14_18 Combo Jones trial V4.9
87:18 - 87:22	**Altonaga, Bill 10-22-2013 (00:00:19)** 87:18 Q. All right. In order to come to the conclusion 87:19 as to whether a device should or should not be recalled, 87:20 would it be important to consider the failure mode 87:21 evaluation and the severity of harm evaluation? 87:22 A. Yes.	05_14_18 Combo Jones trial V4.10
90:15 - 90:22	**Altonaga, Bill 10-22-2013 (00:00:23)** 90:15 Q. Can we agree, however, that the actual 90:16 universe of adverse reports or complications is	05_14_18 Combo Jones trial V4.11

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	90:17 certainly going to be higher than what is actually 90:18 reported? 90:19 A. I have no idea. I have no idea how to answer 90:20 that. I can only respond to if someone reports 90:21 something that needs to be reported, it's reported. How 90:22 many of those would not? I have no idea.	
90:23 - 91:6	**Altonaga, Bill 10-22-2013 (00:00:17)** 90:23 Q. Okay. But I think you told me a little while 90:24 ago you agree that the MDR reporting system doesn't 91:1 capture the universe of adverse events? 91:2 A. Yes. 91:3 Q. Does it then stand to reason that the actual 91:4 number of adverse events is some percentage higher than 91:5 what's actually reported? 91:6 A. I think that's reasonable.	05_14_18 Combo Jones trial V4.12
91:13 - 91:16	**Altonaga, Bill 10-22-2013 (00:00:14)** 91:13 Q. Sir, I'm going to back up for a second. I 91:14 think you indicated when you started at Bard that was in 91:15 2007? 91:16 A. 2008.	05_14_18 Combo Jones trial V4.13
92:18 - 92:24	**Altonaga, Bill 10-22-2013 (00:00:27)** 92:18 Q. All right. And what was your first exposure to 92:19 IVC filters in your career? 92:20 A. My first exposure to IVC filters was at Bard. 92:21 I don't remember exactly when, but it was when I was 92:22 started working at Bard. 92:23 Q. In 2008? 92:24 A. Correct. It may have been after 2008.	05_14_18 Combo Jones trial V4.14
124:18 - 125:18	**Altonaga, Bill 10-22-2013 (00:01:24)** 124:18 Q. And using a severity of harm 124:19 analysis, what's the difference between penetration and 124:20 perforation? Which one poses more risk of harm to the 124:21 patient? 124:22 A. I would think that perforation would increase 124:23 the risk of harm. 124:24 Q. Okay. And why is that? 125:1 A. Just clinically intuitive that if you go all 125:2 the way through a vessel versus just into the vessel 125:3 that there's an increased chance of harm. 125:4 Q. All right. And tell me based on anatomy and	05_14_18 Combo Jones trial V4.15

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	125:5 what have you why perforation poses a greater risk of 125:6 harm to the patient. 125:7 A. First of all, I think it provides a varying 125:8 degree of harm. It doesn't mean the worse case every 125:9 time it perforates. It could mean that in the case of a 125:10 filter, the limb could protrude through the cava and 125:11 touch an adjacent organ or tissue and cause a varying 125:12 degree of injury to that tissue or symptoms to the 125:13 patient as opposed to something that's just penetrated 125:14 or into the wall of the cava. 125:15 Q. And what organs are you referring? 125:16 A. Whatever organs are adjacent to where the 125:17 filter is, so it could be tissue. It could be the 125:18 spine. It could be organs next to the cava, the aorta.	
125:22 - 126:1	**Altonaga, Bill 10-22-2013 (00:00:12)** 125:22 Q. And if there is perforation of the filter 125:23 outside of the vena cava into the aorta, that is likely 125:24 a fatal event, is it not? 126:1 A. No, not necessarily.	05_14_18 Combo Jones trial V4.16
126:2 - 126:3	**Altonaga, Bill 10-22-2013 (00:00:04)** 126:2 Q. Significant likelihood? 126:3 A. I don't know what the likelihood is.	05_14_18 Combo Jones trial V4.17
126:4 - 126:16	**Altonaga, Bill 10-22-2013 (00:00:44)** 126:4 Q. What would be your concern as a person who has 126:5 an M.D. degree knowing anatomy, knowing physiology, if 126:6 the filter protrudes through, perforates through the 126:7 vena cava and into the aorta? 126:8 A. What are you asking? 126:9 Q. What would be your concerns? 126:10 A. My concerns would be that the presence of that 126:11 limb, of whether it's affecting the aorta or not, I 126:12 would certainly rely on images and experts, vascular 126:13 interventionalists, to assess that case. And again, 126:14 it's all about risk-benefit to that patient, but the 126:15 mere fact that it's simply into the aorta doesn't mean 126:16 that I think it's the highest severity of issues.	05_14_18 Combo Jones trial V4.18
135:5 - 135:7	**Altonaga, Bill 10-22-2013 (00:00:05)** 135:5 Q. And are you familiar with the various types of 135:6 fracture that have occurred with the Bard line of 135:7 filters?	05_14_18 Combo Jones trial V4.19

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135:10 - 135:10	**Altonaga, Bill 10-22-2013 (00:00:01)** 135:10 A. Yes.	05_14_18 Combo Jones trial V4.20
135:20 - 136:6	**Altonaga, Bill 10-22-2013 (00:00:43)** 135:20 Q. As part of, again, your job at Bard, in 135:21 terms of performing a severity of harm analysis with a 135:22 fracture of the filter, give us some ideas as to what 135:23 the spectrum of harm would be. 135:24 A. Okay. I would think that it depends on what 136:1 the consequences of the fracture are. So if you have a 136:2 fracture that's identified while the filters in place, 136:3 the limb that has fractured is well incorporated within 136:4 the cava, I would say that that probably poses a less 136:5 risk to the patient than one that has fractured and 136:6 embolized or distally moved away from the filter.	05_14_18 Combo Jones trial V4.21
136:7 - 136:18	**Altonaga, Bill 10-22-2013 (00:00:35)** 136:7 Q. So you do acknowledge that one of 136:8 the problems with fracture can involve the embolization 136:9 of that fracture fragment to other parts of the body? 136:10 A. I am, yes. 136:11 Q. All right. And give us some idea as to the 136:12 organs and parts of the body that a fracture can 136:13 embolize to. 136:14 A. I would say that the most likely place for it 136:15 to fracture would be up through the vena cava into the 136:16 right atrium. Its resting location could be the right 136:17 atrium, it could go into the left ventricle, or it could 136:18 end up in pulmonary circulation.	05_14_18 Combo Jones trial V4.22
137:2 - 137:11	**Altonaga, Bill 10-22-2013 (00:00:34)** 137:2 Q. And what is the clinical significance of a 137:3 piece of an IVC filter embolizing to the heart, the 137:4 pulmonary vasculature, and/or the lung? 137:5 A. I think it has a varying degree of risk 137:6 depending on how it's situated, where it ends up, how 137:7 soon it's detected, how long it sits there. It could be 137:8 clinically insignificant. It could trap itself in a 137:9 place where it doesn't do anything that's been reported, 137:10 or it could cause perforating injuries to -- or tissue 137:11 injury to the heart or the lungs.	05_14_18 Combo Jones trial V4.23
137:12 - 137:22	**Altonaga, Bill 10-22-2013 (00:00:38)** 137:12 Q. Going back to the perforation	05_14_18 Combo Jones trial V4.24

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	137:13 mechanism that we talked about earlier, you indicated 137:14 that the filter could actually protrude through the vena 137:15 cava and into the aorta, for example? 137:16 A. I said it could potentially penetrate into the 137:17 aorta, yes. 137:18 Q. All right. And we discussed the significance 137:19 of that. Can the filter also penetrate through the vena 137:20 cava and injure the kidney, the liver, or any of those 137:21 organs? 137:22 A. I guess it could, yes.	
138:4 - 138:6	**Altonaga, Bill 10-22-2013 (00:00:05)** 138:4 Q. Can perforation extend also into 138:5 the bowel? 138:6 A. It could.	05_14_18 Combo Jones trial V4.25
142:10 - 142:17	**Altonaga, Bill 10-22-2013 (00:00:31)** 142:10 Q. And as a medical doctor, do you acknowledge 142:11 that the vena cava can actually expand by as much up to 142:12 50 percent its resting size? 142:13 A. I believe that that's true. 142:14 Q. Okay. As an example, if an individual has a 142:15 28-millimeter vena cava, given the various dynamics, 142:16 that could actually expand up to 42 millimeters, agreed? 142:17 A. Agreed.	05_14_18 Combo Jones trial V4.26
149:8 - 149:15	**Altonaga, Bill 10-22-2013 (00:00:21)** 149:8 just because certain complications are known to 149:9 occur, isn't it important to know the rate at which 149:10 those complications occur? 149:11 A. Yes. 149:12 Q. All right. And there becomes a point at which 149:13 a complication, a rate becomes unacceptable, does it 149:14 not? 149:15 A. Yes.	05_14_18 Combo Jones trial V4.27
149:16 - 150:1	**Altonaga, Bill 10-22-2013 (00:00:27)** 149:16 Q. All right. And -- so just simply to throw out 149:17 the idea that filters are known to migrate, perforate, 149:18 or fracture, that sort of begs the question, does it 149:19 not, because you have to have an understanding of the 149:20 rate at which that occurs in order to know whether your 149:21 complication rate is either acceptable or not 149:22 acceptable?	05_14_18 Combo Jones trial V4.28

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	149:23 A. Okay. 149:24 Q. Do you agree? 150:1 A. I don't disagree with that.	
150:2 - 150:11	**Altonaga, Bill 10-22-2013 (00:00:32)** 150:2 Q. And going back to this deposition when 150:3 it started earlier, one of the things that would be 150:4 important to do would be to compare the 510(k) device's 150:5 complication rate, its safety profile, to that of the 150:6 predicate device. Agreed? 150:7 A. To some extent, yes. 150:8 Q. All right. 150:9 A. But as I said, they may not be apples to 150:10 apples, so you have to take into consideration the data 150:11 sets for which those rates came about.	05_14_18 Combo Jones trial V4.29
152:6 - 152:10	**Altonaga, Bill 10-22-2013 (00:00:10)** 152:6 Q. Bard's required to be 152:7 transparent and upfront with all information, whether 152:8 it's good or bad? 152:9 A. I would think that they're required to do so, 152:10 yes.	05_14_18 Combo Jones trial V4.30
152:11 - 152:14	**Altonaga, Bill 10-22-2013 (00:00:11)** 152:11 Q. And that also includes conveying bad 152:12 information to the doctors that are implanting these 152:13 devices, correct? 152:14 A. What do you mean by bad information?	05_14_18 Combo Jones trial V4.31
152:16 - 152:16	**Altonaga, Bill 10-22-2013 (00:00:02)** 152:16 Q. Rate of complications, for example.	05_14_18 Combo Jones trial V4.32
152:17 - 152:20	**Altonaga, Bill 10-22-2013 (00:00:12)** 152:17 A. No, I don't -- I don't think that -- that is a 152:18 responsibility of a medical device company to provide 152:19 rates. If they're asked or solicited, we may provide 152:20 that.	05_14_18 Combo Jones trial V4.49
152:24 - 153:7	**Altonaga, Bill 10-22-2013 (00:00:23)** 152:24 Q. And what is a warning and what's the 153:1 purpose behind issuing a warning to a physician or 153:2 healthcare provider that is using a Bard device? 153:3 A. Just like the warnings that are provided in the 153:4 instructions for use of every medical device. It's 153:5 known or identified events that may put the patient at 153:6 risk, whether it's in the form of contraindication or	05_14_18 Combo Jones trial V4.33

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	153:7 precaution or warning.	
153:8 - 153:11	**Altonaga, Bill 10-22-2013 (00:00:16)**	05_14_18 Combo Jones trial V4.34
	153:8 Q. If Bard became aware that one of its filters 153:9 had a failure rate that exceeded the industry average by 153:10 three times, 300 percent higher, in your opinion, would 153:11 Bard be obligated to warn of that fact?	
153:17 - 153:20	**Altonaga, Bill 10-22-2013 (00:00:08)**	05_14_18 Combo Jones trial V4.35
	153:17 A. I don't know how to answer that. It depends on 153:18 the issue. It depends on the severity of harm. It 153:19 depends on a lot of different variables. So it's a very 153:20 open question. I don't know.	
154:5 - 154:12	**Altonaga, Bill 10-22-2013 (00:00:23)**	05_14_18 Combo Jones trial V4.36
	154:5 Q. if Bard is aware that the 154:6 migration rate of one of its filters exceeds industry 154:7 average by three times -- we've already spoken about the 154:8 spectrum of harm that can attach to a migrating filter. 154:9 Do you recall that? 154:10 A. Yes. 154:11 Q. All right. Would Bard, under those 154:12 circumstances, be obligated to warn of that fact?	
155:4 - 155:10	**Altonaga, Bill 10-22-2013 (00:00:23)**	05_14_18 Combo Jones trial V4.37
	155:4 A. The reason I'm having difficulty with your 155:5 question is because the warning regarding migration has 155:6 already been posed. So you're asking if over and above 155:7 a warning that's already been posed, something that's 155:8 been well understood with the use of all IVC filters, 155:9 that why would Bard feel more obligated to warn again. 155:10 So I -- the warning's already there.	
157:19 - 158:4	**Altonaga, Bill 10-22-2013 (00:00:25)**	05_14_18 Combo Jones trial V4.38
	157:19 THE COURT REPORTER: "Would it be your 157:20 expectation that when Bard launches a filter for 157:21 commercial use that Bard would have an awareness 157:22 about the long-term clinical performance of that 157:23 device?" 157:24 A. Yes. 158:1 Q. Why? Why would that be important? 158:2 A. Because I think it's prudent for the medical 158:3 device company to understand how its device performs 158:4 regarding safety and effectiveness.	
158:5 - 158:6	**Altonaga, Bill 10-22-2013 (00:00:06)**	05_14_18 Combo Jones trial V4.39

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	158:5 Q. And how would you expect Bard to develop that 158:6 awareness with its IVC filter?	
158:10 - 158:12	**Altonaga, Bill 10-22-2013 (00:00:06)** 158:10 A. Based on postmarket surveillance, based on 158:11 literature, based on clinical trials, a lot of different 158:12 ways.	05_14_18 Combo Jones trial V4.40
158:18 - 158:21	**Altonaga, Bill 10-22-2013 (00:00:16)** 158:18 Q. if Bard didn't have an awareness about 158:19 the long-term clinical performance of an IVC filter, yet 158:20 its being implanted into individuals, does that become 158:21 problematic in your mind?	05_14_18 Combo Jones trial V4.41
158:23 - 159:3	**Altonaga, Bill 10-22-2013 (00:00:09)** 158:23 A. If they were not aware, yes, I think that would 158:24 be problematic. 159:1 Q. Okay. Why would that be problematic? 159:2 A. Because you don't know how your product is 159:3 performing.	05_14_18 Combo Jones trial V4.42
168:5 - 168:9	**Altonaga, Bill 10-22-2013 (00:00:15)** 168:5 Q. Well, you're a medical doctor, and do you at 168:6 least acknowledge that the more information a clinical 168:7 physician has, the better he or she can make decisions 168:8 about what medical device to use in a particular 168:9 patient?	05_14_18 Combo Jones trial V4.43
168:12 - 168:13	**Altonaga, Bill 10-22-2013 (00:00:02)** 168:12 A. In very general terms, I don't disagree with 168:13 that.	05_14_18 Combo Jones trial V4.44
243:16 - 243:18	**Altonaga, Bill 10-22-2013 (00:00:08)** 243:16 Don't you think that the 243:17 doctors who are implanting these devices should be aware 243:18 of these significant differences in the safety profile?	05_14_18 Combo Jones trial V4.45
243:20 - 243:21	**Altonaga, Bill 10-22-2013 (00:00:06)** 243:20 A. I think that the doctors should be aware of the 243:21 rates of complications associated with these devices. I	05_14_18 Combo Jones trial V4.46
243:21 - 244:1	**Altonaga, Bill 10-22-2013 (00:00:13)** 243:21 I 243:22 think that there's also other things that need to be 243:23 considered. You know, one is retrievable, one wasn't, 243:24 so there's a lot of safety profile issues not discussed 244:1 here that I think need to play into the equation.	05_14_18 Combo Jones trial V4.47
251:3 - 251:6	**Altonaga, Bill 10-22-2013 (00:00:08)**	05_14_18 Combo Jones trial V4.48

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251:3 Q. Did Bard, to your knowledge, ever sponsor a
251:4 randomized clinical trial to assess the safety of the
251:5 Recovery Filter?
251:6 A. That I'm aware of, no.

Plaintiffs Designations = 00:11:34
Defense Designations = 00:06:02
P & D Designations = 00:00:04
Total Time = 00:17:40

Exhibit B

Designation Run Report

Avino 03-23-17 Jones Trial Run V7.1

Avino, Anthony 03-23-2017

Plaintiff Designations 00:12:20

Defense Designations 00:26:31

Plaintiff and Defense Designations 00:04:48

Total Time 00:43:39

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8:1 - 8:3	**Avino, Anthony 03-23-2017 (00:00:09)** 8:1 So why don't we start by introducing 8:2 yourself to the jury. 8:3 A. Okay. Anthony Avino.	05_21_18 Combo Jones V7_1.1
12:2 - 12:10	**Avino, Anthony 03-23-2017 (00:00:38)** 12:2 Q. Explain to the jury, as a vascular 12:3 surgeon, what your average or typical day is like. 12:4 A. Fairly varied. It's basically everything 12:5 that has to do with arteries and veins, and it really 12:6 ranges from spider veins, to a lot of catheters and 12:7 ports, to a lot of angioplasties for blockages in 12:8 arteries in the arms and legs, and then a lot of open 12:9 surgery on arteries and veins, again in the arms, 12:10 legs, belly or chest, just not in the heart.	05_21_18 Combo Jones V7_1.2
13:2 - 13:13	**Avino, Anthony 03-23-2017 (00:00:38)** 13:2 we're here today because of your 13:3 implanting of IVC filter in Doris Jones in 2010. In 13:4 2010, you were practicing here? 13:5 A. Yes. 13:6 Q. Where did you see Doris Jones? 13:7 A. In consultation in the hospital at 13:8 Memorial. 13:9 Q. And did you ever see or follow up with her 13:10 again after you implanted the IVC filter in her? 13:11 A. I don't believe so. Certainly not that I 13:12 have independent recollection, and not that I see 13:13 from our records	05_21_18 Combo Jones V7_1.3
13:24 - 14:5	**Avino, Anthony 03-23-2017 (00:00:11)** 13:24 Q. As a vascular surgeon, you use 13:25 medical devices? 14:1 A. Yes. 14:2 Q. Lots of different kinds of medical 14:3 devices, presumably. You mentioned some earlier; 14:4 catheters and ports and things like that. Fair? 14:5 A. Right. Fair.	05_21_18 Combo Jones V7_1.4
16:7 - 17:2	**Avino, Anthony 03-23-2017 (00:00:51)** 16:7 Q. Given that you work with so many different 16:8 medical devices and manufacturers and talking to 16:9 sales reps, I would imagine you have certain 16:10 expectations for medical device manufacturers; for	05_21_18 Combo Jones V7_1.5

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	16:11 example, that the devices that they would put on the 16:12 market for use in your patients are safe? 16:13 A. Agree, yes. 16:14 Q. And that they're effective; that they do 16:15 what they're supposed to do? 16:16 A. Yes. 16:17 Q. And I would imagine you expect that a 16:18 medical device manufacturer's primary focus should be 16:19 on the health and safety of patients? 16:20 A. Primarily, yep, absolutely. 16:21 Q. And that means putting the safety of 16:22 patients ahead of profits? 16:23 A. Right. 16:24 Q. And you would expect the medical devices 16:25 you use would -- would make the harm they're intended 17:1 to treat better, not worse? 17:2 A. Agree.	
17:10 - 17:20	**Avino, Anthony 03-23-2017 (00:00:17)** 17:10 Q. And you would expect that a medical device 17:11 manufacturer would take all reasonable steps to make 17:12 sure that a device is safe and free of danger before 17:13 putting the device on the market? 17:14 A. I would. 17:15 Q. Including reasonable testing to ensure the 17:16 safety of the device? 17:17 A. Yes. 17:18 Q. And clinical trials to ensure that the 17:19 device is safe for use? 17:20 A. Yes.	05_21_18 Combo Jones V7_1.6
18:3 - 18:8	**Avino, Anthony 03-23-2017 (00:00:13)** 18:3 Q. You would expect that the risks and 18:4 dangers of a medical device should be known by the 18:5 manufacturers through their own development and 18:6 testing of their product before it's put on the 18:7 market? 18:8 A. The -- both the manufacturers and the FDA.	05_21_18 Combo Jones V7_1.7
21:2 - 21:18	**Avino, Anthony 03-23-2017 (00:00:42)** 21:2 Q. If a medical device manufacturer learns 21:3 that a device is less safe than alternative 21:4 treatments or other alternative products by other	05_21_18 Combo Jones V7_1.8

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	21:5 competitors, would you expect them to report that to 21:6 you and other doctors? 21:7 A. I mean, we certainly always expect that 21:8 they report anything that's not safe to the FDA and 21:9 to the physicians. 21:10 Q. And you need to know information about 21:11 safety to make informed decisions about using 21:12 products? 21:13 A. True. 21:14 Q. And because you're advising patients, and 21:15 they can't make informed consent about using products 21:16 unless you have all the information to inform them. 21:17 True? 21:18 A. True.	
21:19 - 21:24	**Avino, Anthony 03-23-2017 (00:00:18)** 21:19 Q. And the information that a medical device 21:20 manufacturer provides to you about their product, you 21:21 would expect that to be accurate and complete. True? 21:22 A. Sure, to the best -- you know, certainly 21:23 to the best of whatever knowledge they have acquired 21:24 regarding safety and problems.	05_21_18 Combo Jones V7_1.9
24:10 - 25:6	**Avino, Anthony 03-23-2017 (00:01:11)** 24:10 Q. What are the criteria for determining if 24:11 an IVC filter is appropriate for a patient? 24:12 A. It's mostly -- the general indication and 24:13 decision-making is if the risk of placing the filter 24:14 is lower than the risk of not placing the filter. So 24:15 if they're at higher risk for throwing a clot without 24:16 the filter, and that's mostly in people who have a 24:17 clot and for one of numerous reasons cannot fully be 24:18 on blood thinners to prevent the clot from worsening 24:19 or propagating and embolizing, or breaking off and 24:20 moving. 24:21 So if someone has surgery, a recent 24:22 surgery, or bleeding complications and they have 24:23 clots, or they have clots that keep worsening despite 24:24 blood thinners, then that's -- that's the main 24:25 indication for placing a filter. 25:1 And then there's a lot of relative 25:2 indications. People that are just really high-risk,	05_21_18 Combo Jones V7_1.11

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	25:3 people that are bedridden, and people that have had 25:4 past clots and who have bleeding complications and 25:5 can't receive blood thinners. And there's numerous 25:6 reasons people can't receive blood thinners.	
26:2 - 26:7	**Avino, Anthony 03-23-2017 (00:00:18)** 26:2 Q. Putting in an IVC filter, you know, 26:3 threading this sheath through the heart into the IVC 26:4 through a vein in your neck, to a layperson, to me, 26:5 that sounds really scary and dangerous. But is this 26:6 a risky procedure in the spectrum of work that you do 26:7 as a vascular surgeon?	05_21_18 Combo Jones V7_1.12
26:9 - 26:25	**Avino, Anthony 03-23-2017 (00:00:44)** 26:9 THE WITNESS: It's one of the least risky 26:10 procedures that we do. 26:11 BY MR. COMBS: 26:12 Q. Explain why that -- why it's safe, when -- 26:13 even though you're involving all these central organs 26:14 and all that. 26:15 A. Right. For years, physicians have 26:16 performed instrumentation, or passing catheters and 26:17 wires through veins or arteries, really from any 26:18 location to any location, as long as you've done it 26:19 enough and are careful and cautious and you do it all 26:20 under direct visualization with x-ray. 26:21 And that's really why it's safe, because 26:22 you're traveling in a vein; you're on the inside of a 26:23 vein, and if at any point you're traveling outside of 26:24 the vein, you can see it immediately because you're 26:25 watching it all on x-ray, live.	05_21_18 Combo Jones V7_1.13
27:22 - 28:8	**Avino, Anthony 03-23-2017 (00:00:31)** 27:22 Q. How -- I don't know the best way to ask 27:23 this; of how many IVC filters you've put in, a week, 27:24 or a month or what percentage of your practice is IVC 27:25 filter? But just talk about your experience of IVC 28:1 filters and how that relates to the rest of your 28:2 clinical practice. 28:3 A. I've -- it's always a guess to try to 28:4 remember, because I've practiced more years than 28:5 there -- than I have memory of, I guess. But I've 28:6 probably put -- I would guess I've put in two or	05_21_18 Combo Jones V7_1.14

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	28:7 three hundred. It's -- but it's still a small 28:8 percentage of my practice.	
30:1 - 30:23	**Avino, Anthony 03-23-2017 (00:01:08)** 30:1 Q. And as I understand it, some IVC filters 30:2 are permanent and some are optional or retrievable; 30:3 is that correct? 30:4 A. Yes. 30:5 Q. Explain to the jury the difference between 30:6 a permanent IVC filter and a retrievable or optional 30:7 IVC filter. 30:8 A. All of the original filters were 30:9 considered permanent, and there really was no 30:10 technology or mechanism to remove them. And that was 30:11 the case for decades. And we, you know, it just -- 30:12 there was never even a consideration or a thought of 30:13 retrieving them. But over time, when more long-term 30:14 concerns arose about leaving these filters in young 30:15 patients, especially, for their whole lifetime, 30:16 technology evolved that there was a fairly simple 30:17 mechanism, basically a hook on top of the filter, 30:18 that you could snag the hook, and with a special 30:19 device, actually retrieve the filter by causing it to 30:20 collapse inside the vein, once you have it secured by 30:21 this snare. So basically it was a change in design 30:22 of the technology to allow the filter to safely be 30:23 removed.	05_21_18 Combo Jones V7_1.15
31:2 - 31:13	**Avino, Anthony 03-23-2017 (00:00:40)** 31:2 but why would you 31:3 use a permanent filter versus a retrievable filter? 31:4 A. In someone elderly, in someone who has a 31:5 long-term risk of clots breaking off and going to 31:6 their heart and lungs, for example, someone who is 31:7 either noncompliant or has felt to be a long-term 31:8 risk of recurrent bleeding, someone that has 31:9 cirrhosis or medical conditions that cause them to 31:10 have -- to become more prone to bleed, someone that 31:11 falls frequently. So basically someone that has an 31:12 ongoing risk. And someone who is elderly; those two 31:13 reasons.	05_21_18 Combo Jones V7_1.91
33:21 - 34:6	**Avino, Anthony 03-23-2017 (00:00:36)**	05_21_18 Combo Jones V7_1.16

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	33:21 Q. I guess, since you've been here in 33:22 this practice, Savannah, for -- since completing your 33:23 training, since you've been here, what IVC filter 33:24 models have you used, including up until today? 33:25 Which ones do you use? 34:1 A. We have predominantly always used -- I 34:2 won't say "always"; we have predominantly used the 34:3 Bard filters. The G2 and the Simon Nitinol was the 34:4 nonretrievable, and the Meridian and now the Denali. 34:5 And a couple in between. They've changed every few 34:6 years.	
34:10 - 34:20	**Avino, Anthony 03-23-2017 (00:00:33)** 34:10 Q. And why have -- well, when you say -- when 34:11 you talk about using predominantly Bard IVC filters, 34:12 does that go for your whole practice group here? 34:13 A. Predominantly. You know, there's Cook 34:14 filters, and there's other competitors' filters. 34:15 There's the original Greenfield IVC filter. But we 34:16 have mostly always stocked -- I would say yes, 34:17 definitely yes, the majority of them that we see 34:18 placed by myself and all my partners have always been 34:19 the Bard filters. 34:20 Q. And why is that?	05_21_18 Combo Jones V7_1.17
34:22 - 35:6	**Avino, Anthony 03-23-2017 (00:00:28)** 34:22 There has been the most 34:23 data on them, and I think they're likely -- it's 34:24 certainly variable from institution to institution, 34:25 but everywhere I've been, they've been the 35:1 predominant filter. 35:2 Q. And today -- when was the last time you 35:3 put an IVC filter in somebody? 35:4 A. About two weeks ago. 35:5 Q. And what device did you use then? 35:6 A. The Denali.	05_21_18 Combo Jones V7_1.18
35:12 - 35:16	**Avino, Anthony 03-23-2017 (00:00:15)** 35:12 Q. Do you still put permanent filters in 35:13 patients, in the last six months? 35:14 A. Yes, I do. And as far as I know, the -- I 35:15 think it's still the Simon Nitinol. I think it's 35:16 still the Simon Nitinol brand.	05_21_18 Combo Jones V7_1.19

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35:17 - 36:3	**Avino, Anthony 03-23-2017 (00:00:25)** 35:17 Q. Any time you put any medical device in 35:18 somebody, including an IVC filter, I know you do it 35:19 every day, but that's still a big deal for the 35:20 patient, right? 35:21 A. Sure. 35:22 Q. You're putting some kind of object for a 35:23 long period of time, maybe permanently, inside their 35:24 body. Right? 35:25 A. Yes. 36:1 Q. And so whenever you do that, safety is 36:2 always your number one priority? 36:3 A. Agree.	05_21_18 Combo Jones V7_1.20
36:4 - 36:25	**Avino, Anthony 03-23-2017 (00:01:12)** 36:4 Q. You touched on this, but I want you to, if 36:5 you can, explain to the jury a little bit more about 36:6 the risk/benefit analysis you do when placing an IVC 36:7 filter in one of your patients. 36:8 A. So on the benefit side, the benefit of 36:9 having the filter is that there is a lower chance of 36:10 dying from a pulmonary embolus if they have a filter 36:11 in place. And so you have to weigh -- I mean, 36:12 obviously the complication is catastrophic. It's not 36:13 like, you know, getting an infection somewhere. It's 36:14 a pulmonary embolus, which often means death. 36:15 So it's a matter of weighing what their -- 36:16 trying to make an assessment of what their risk of 36:17 death is, and risk of pulmonary embolus, how they 36:18 would tolerate it, and if there's a high or low risk 36:19 of that actually occurring. 36:20 And then you have to weigh that with the 36:21 risks of placing the procedure, not just the risks, 36:22 but the costs and the time and the pain -- not that 36:23 there's a lot of pain, but, you know, it's still a 36:24 procedure, the anxiety. And then the potential 36:25 long-term complications that we've mentioned.	05_21_18 Combo Jones V7_1.21
38:11 - 38:13	**Avino, Anthony 03-23-2017 (00:00:08)** 38:11 Q. Did you ever talk with any Bard sales 38:12 representatives about IVC filters? 38:13 A. Yes.	05_21_18 Combo Jones V7_1.22

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38:19 - 38:21	**Avino, Anthony 03-23-2017 (00:00:10)** 38:19 Q. Okay. Who were they? 38:20 A. Well, I know that it was Melanie Vilece 38:21 for my middle years here.	05_21_18 Combo Jones V7_1.23
39:15 - 40:1	**Avino, Anthony 03-23-2017 (00:00:43)** 39:15 Q. Do you recall conversations with 39:16 her, or any other Bard sales reps, about Bard IVC 39:17 filters, what you guys talked about? 39:18 A. Well, I do, because it -- the -- obviously 39:19 for the reasons we're here, the IVC filters became a 39:20 big hot topic when it was -- when it became more well 39:21 known that there were complications. 39:22 And so, yes, we would talk about 39:23 complications, and we would talk about -- you know, 39:24 the FDA, and the next generation of filters, and 39:25 improvements that were under way, and -- you know, 40:1 and what -- and what the complications were.	05_21_18 Combo Jones V7_1.24
40:5 - 40:13	**Avino, Anthony 03-23-2017 (00:00:20)** 40:5 The IVC filter model that was put 40:6 into Doris Jones, my client, was an Eclipse model. 40:7 Are you aware of that? 40:8 A. Yes. 40:9 Q. Do you recall any conversations with 40:10 Ms. Vilece or anyone else at Bard about the Eclipse, 40:11 specifically, and if so, what they told you about the 40:12 Eclipse? 40:13 A. I really don't.	05_21_18 Combo Jones V7_1.25
40:13 - 40:21	**Avino, Anthony 03-23-2017 (00:00:37)** 40:13 A. I don't have specific 40:14 recollection about the individual devices, except 40:15 that, you know, the G2 I think was the one that was 40:16 known to be the biggest problem, whenever that became 40:17 evident, and then was quickly replaced. 40:18 Q. And when you say the G2 became the biggest 40:19 problem, what was the problem with the G2? 40:20 A. That's the device that had the biggest 40:21 reports about migrations and fractures in the device.	05_21_18 Combo Jones V7_1.26
40:22 - 41:10	**Avino, Anthony 03-23-2017 (00:00:39)** 40:22 Q. was it a kind of thing where you guys 40:23 collectively, at the practice, liked using the Bard	05_21_18 Combo Jones V7_1.27

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	40:24 IVC filters, and so whenever they came out with a new 40:25 one, you would just kind of incorporate and adopt the 41:1 new one into your practice? 41:2 A. Yes. You know, assuming -- yes, because 41:3 that was always congruent with what we were also 41:4 being told, you know, from our literature, from our 41:5 journals, from the reps, from our meetings; you know, 41:6 all of the above. 41:7 So because that was true, it wasn't like 41:8 it just showed up and -- you know, someone said it 41:9 was cool, or it was -- for all of those reasons, 41:10 that, but yes.	
41:11 - 41:23	**Avino, Anthony 03-23-2017 (00:00:43)** 41:11 Q. And tell the jury a little bit 41:12 about the other ways you learned about IVC filters 41:13 and developments in the field, besides talking with 41:14 the Bard sales rep, or other sales rep. 41:15 A. We all attend meetings annually, usually 41:16 several. And, you know, meetings might have -- our 41:17 main meeting in New York might have 200 or 300 41:18 topics, you know. Crazy volume. 41:19 And -- but medical devices are certainly a 41:20 large percentage of what the topics are about, and so 41:21 those are usually presentations, and the person 41:22 chosen to give the presentation is very selectively 41:23 chosen to be considered an expert in that field.	05_21_18 Combo Jones V7_1.92
41:24 - 42:3	**Avino, Anthony 03-23-2017 (00:00:13)** 41:24 And so that's the -- one of the main ways, 41:25 because this is someone that's reviewed all the 42:1 literature and someone that's well known and 42:2 respected by your colleagues. So that's -- that's a 42:3 common area.	05_21_18 Combo Jones V7_1.93
42:4 - 42:10	**Avino, Anthony 03-23-2017 (00:00:18)** 42:4 There's certainly advertisements in 42:5 magazines from manufacturers. There's sales reps. 42:6 There's discussions with your colleagues. And then 42:7 there's articles written in journals. 42:8 So, really, all of the above. It's 42:9 inundated with online journals and so -- choice E: 42:10 All of the above.	05_21_18 Combo Jones V7_1.28

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47:11 - 47:13	**Avino, Anthony 03-23-2017 (00:00:07)** 47:11 Q. do you read the IFU? 47:12 A. Sometimes. I mean, I have read them. I 47:13 don't -- certainly don't read them on every package,	05_21_18 Combo Jones V7_1.29
47:14 - 47:20	**Avino, Anthony 03-23-2017 (00:00:24)** 47:14 because they're the same from the same device, but -- 47:15 you know, not -- not all the time, but it does come 47:16 up, for example, at meetings, or you're reading about 47:17 and someone's discussing an issue with an IFU. You 47:18 know, if something is within the IFU or not, to help 47:19 define things that might be outside of the IFU but 47:20 still medically indicated.	05_21_18 Combo Jones V7_1.30
47:21 - 47:23	**Avino, Anthony 03-23-2017 (00:00:07)** 47:21 Q. Do you know if you ever read the IFU for 47:22 the Eclipse IVC filter? 47:23 A. Not that I recall.	05_21_18 Combo Jones V7_1.31
47:24 - 48:7	**Avino, Anthony 03-23-2017 (00:00:28)** 47:24 Q. Okay. And IFUs have warnings on them of 47:25 side effects, complications, things like that, also? 48:1 A. Yes. 48:2 Q. And even if you haven't read the Eclipse 48:3 IFU, you're probably generally familiar with IVC 48:4 filter IFUs, if they warn of things like fractures, 48:5 migration, perforation, tilt; complications like 48:6 that. Right? 48:7 A. Yes. Yes.	05_21_18 Combo Jones V7_1.32
48:20 - 49:14	**Avino, Anthony 03-23-2017 (00:00:53)** 48:20 Q. If you can recall your mindset in 48:21 August 2010, when you implanted the Eclipse in Doris 48:22 Jones, what was your understanding of the rarity of 48:23 complications from IVC filters then? 48:24 A. I don't have independent recollection of 48:25 placing that particular filter, but the best I can 49:1 tell from that date and from my note, is that that 49:2 is -- that predates the peak of my concern and the 49:3 release of the warnings about the complications of 49:4 filters. 49:5 Q. You've learned more about filters since 49:6 then -- 49:7 A. Right.	05_21_18 Combo Jones V7_1.33

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	49:8 Q. -- and their complications? 49:9 A. Right. 49:10 Q. If Bard knew about complications with its 49:11 filters at that time, before you put it -- one in 49:12 Doris Jones, you would have wanted to know that, 49:13 right? 49:14 A. Yes.	
50:15 - 50:20	**Avino, Anthony 03-23-2017 (00:00:17)** 50:15 Q. So in front of you now, Doctor, 50:16 Exhibit 4017, is your op notes for the implantation 50:17 with Doris Jones. Correct? 50:18 A. Yes. 50:19 Q. And what date was that? 50:20 A. August 24th, 2010.	05_21_18 Combo Jones V7_1.34 4401_IMPLANT.1.1
51:1 - 51:16	**Avino, Anthony 03-23-2017 (00:00:42)** 51:1 There probably would be some note in the medical 51:2 record from the hospital, but I never -- it's not 51:3 part of our record, our medical record. 51:4 (Exhibit 4018 was marked for identification.) 51:5 BY MR. COMBS: 51:6 Q. And I think you're actually right. And 51:7 what you've been handed here, Exhibit 4018, is some 51:8 other medical records, including the consent forms 51:9 for the procedure. And I believe they were signed 51:10 the day before, on the 23rd. Do you see that? 51:11 A. Yes. So I -- there is almost always a 51:12 consultation, though, before, just when we see the 51:13 patient, make the decision, talk to the patient, 51:14 consider the data in order to communicate back to the 51:15 other physicians. So there would have been some 51:16 other note.	05_21_18 Combo Jones V7_1.35 clear
51:17 - 52:12	**Avino, Anthony 03-23-2017 (00:00:59)** 51:17 Q. And so I'll ask you about your treatment 51:18 of Doris, brief as it was, and -- and your 51:19 discussions with her and her husband. And so to the 51:20 extent you need to refer back to any of this -- and 51:21 I'll ask you some specific questions about this, 51:22 too -- but if you need to look at any of this to 51:23 refresh your recollection, go ahead. 51:24 Do you recall how you came to treat Doris,	05_21_18 Combo Jones V7_1.94

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	51:25 who called you or consulted with you? 52:1 A. I do not. I'm not sure if it was -- well, 52:2 actually, I take it back. The most likely person is 52:3 Dr. Goodman, because I specifically sent him a copy 52:4 of the note, so that would -- but I don't have 52:5 independent recollection of that, but that's usually 52:6 who would -- usually, I would -- just knowing my 52:7 practice, I would send a copy of the note to the 52:8 person who asked me to see the patient. 52:9 Q. And who is Dr. Goodman? 52:10 A. He's a cardiologist and works with the 52:11 residency program, and also did general medicine, not 52:12 just cardiology.	
52:22 - 54:10	**Avino, Anthony 03-23-2017 (00:02:19)** 52:22 Q. Do you know why the referring 52:23 doctor, Dr. Goodman, called you in to consult in this 52:24 and see about an IVC filter? 52:25 A. Because a concern about her history of 53:1 having had recurrent blood clots, as well as problems 53:2 with multiple gastrointestinal problems and concern 53:3 over bleeding issues and need to stop her 53:4 anticoagulation over different time periods. So it 53:5 basically is a whole combination of having an 53:6 increased risk of complications from her blood clots. 53:7 Q. And you'll see here, on the portion of 53:8 Exhibit 4018 that ends in Bates number 1292, there's 53:9 a sticker on there for a Bard Eclipse IVC filter, 53:10 right? 53:11 A. Yes. 53:12 Q. And was -- can you tell anything, from 53:13 either your recall or looking at these records, why 53:14 that filter was chosen for Doris? 53:15 A. It was probably the only retrievable 53:16 filter that we used at the time and that the hospital 53:17 stocked. And from my note, I indicated that we were 53:18 sort of between wanting the option to be able to 53:19 retrieve the filter, but I even -- but I mentioned 53:20 that we would, I said, "suspecting that this would 53:21 likely remain permanent," meaning that her risk is 53:22 probably not going to go away.	05_21_18 Combo Jones V7_1.36

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	53:23 Complicated patient, in and out of the 53:24 hospital frequently, with multiple problems and 53:25 multiple prior clots. And so for all those reasons, 54:1 you know, she did not have transient risk factors. 54:2 She had persistent risk factors. 54:3 Q. And so essentially she was -- the intent 54:4 was that she would have a permanent filter? 54:5 A. Just slightly short of that, because it 54:6 retains the option to remove it, because if a filter 54:7 does clot off, it's a problem if you can't remove it. 54:8 So there's some advantages to having a retrievable 54:9 filter, if you, even if you think it's going to stay 54:10 in long term.	
54:11 - 54:13	**Avino, Anthony 03-23-2017 (00:00:05)** 54:11 Q. Right, but certainly she could keep it in 54:12 permanently; that was the intent? 54:13 A. Yes.	05_21_18 Combo Jones V7_1.37
54:16 - 54:23	**Avino, Anthony 03-23-2017 (00:00:16)** 54:16 on the first page of your 54:17 op report, it says: "After a long discussion with 54:18 the patient, she opted for a retrievable filter, 54:19 suspecting this would likely remain permanent." 54:20 Do you recall that -- anything about that 54:21 discussion? I don't imagine you do, since you don't 54:22 remember Doris. 54:23 A. No, I really don't.	05_21_18 Combo Jones V7_1.38 4401_IMPLANT.1.2 clear
56:9 - 56:12	**Avino, Anthony 03-23-2017 (00:00:10)** 56:9 Q. And the forms there are just 56:10 general procedure consent forms, not specific to IVC 56:11 filters, right? 56:12 A. Correct.	05_21_18 Combo Jones V7_1.39
56:22 - 56:25	**Avino, Anthony 03-23-2017 (00:00:10)** 56:22 Q. And the information you provide in those 56:23 discussions about the risks and benefits of a device 56:24 are only as good as the information the manufacturer 56:25 gives you?	05_21_18 Combo Jones V7_1.40
57:4 - 57:5	**Avino, Anthony 03-23-2017 (00:00:03)** 57:4 A. Well, the manufacturer or whatever other 57:5 sources we have.	05_21_18 Combo Jones V7_1.41
57:6 - 57:7	**Avino, Anthony 03-23-2017 (00:00:02)**	05_21_18 Combo Jones V7_1.42

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	57:6 Q. Right. 57:7 A. We have our other sources as well.	
57:8 - 57:16	**Avino, Anthony 03-23-2017 (00:00:26)** 57:8 Q. But if a company fails to provide accurate 57:9 or complete information about the risks and benefits 57:10 of its device, that affects your ability to 57:11 adequately inform the patient? 57:12 A. Yes, since that's one of the sources of 57:13 information. 57:14 Q. Did you have any problems implanting the 57:15 IVC filter in Doris? 57:16 A. From my note, I don't think so.	05_21_18 Combo Jones V7_1.43
58:2 - 58:10	**Avino, Anthony 03-23-2017 (00:00:23)** 58:2 Q. if you had any complications or if 58:3 she had an unusual anatomy, like an overly large IVC 58:4 where you would have worries about securing the IVC 58:5 filter, you would have noted that in your report? 58:6 A. Right. 58:7 Q. Or if you were aware that it had been put 58:8 in malpositioned or somehow off or had difficulty 58:9 with it, you would have noted that in your report? 58:10 A. Yes.	05_21_18 Combo Jones V7_1.44
60:17 - 60:20	**Avino, Anthony 03-23-2017 (00:00:10)** 60:17 Q. And then I think we have established that 60:18 you never saw or treated Doris again after this 60:19 implant? 60:20 A. Not that I have any record of, or recall.	05_21_18 Combo Jones V7_1.45
62:24 - 63:18	**Avino, Anthony 03-23-2017 (00:01:01)** 62:24 We've talked about the different models of 62:25 the Bard IVC filters over the years. Were you aware 63:1 that one of the reasons that Bard came out with the 63:2 different versions of its IVC filters was to try to 63:3 address problems with its filters fracturing? 63:4 A. Yes. In that, you know, there were 63:5 always -- we know there were always complications, 63:6 some complications of them and that they were -- you 63:7 know, it just seemed like the filters were similar to 63:8 all of the stents we used, the -- basically, there's 63:9 always one out in the market and there's one always 63:10 under R&D that's the next generation, trying to	05_21_18 Combo Jones V7_1.46

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	63:11 improve upon either patency or lower complications 63:12 or -- so we knew there was always one, you know, just 63:13 from this pattern, it became evident that there was 63:14 always another -- another one -- another one coming. 63:15 If that answers your questions. 63:16 Q. Another model of the Bard IVC filters 63:17 coming? 63:18 A. Right, right.	
63:19 - 64:7	**Avino, Anthony 03-23-2017 (00:00:40)** 63:19 Q. Do you have any idea what those rates of 63:20 complications or fractures were for Bard IVC filters 63:21 or any other manufacturer? 63:22 A. I mean, we were given different -- you 63:23 know, you would hear different numbers from different 63:24 sources. You'd hear a different presentation at a 63:25 talk, that might talk about certain complications 64:1 based on one study, and then there's retrospective 64:2 studies; there's the meta-analyses of combining 64:3 multiple studies. 64:4 So there is -- there just is no one 64:5 answer, you know, to tell you that there was any 64:6 specific number. But I don't have a specific number 64:7 in my mind.	05_21_18 Combo Jones V7_1.47
64:7 - 64:16	**Avino, Anthony 03-23-2017 (00:00:43)** 64:7 But certainly not back years ago. 64:8 Q. Right. Do you -- do you have any, like, 64:9 ballpark in your head of what would be an acceptable 64:10 rate of fractures for an IVC filter? 64:11 A. No. I mean, obviously we want it to be 64:12 very low. Our initial understanding was that the 64:13 fracture rate was very low, in the 5 percent range; 64:14 and then at some point, you know, maybe in the last 64:15 four years or so, is when we learned that they were 64:16 higher than that. Or maybe six years, or three,	05_21_18 Combo Jones V7_1.48
67:9 - 67:14	**Avino, Anthony 03-23-2017 (00:00:11)** 67:9 (Exhibit 4020 was marked for identification.) 67:10 BY MR. COMBS: 67:11 Q. the next document is a product 67:12 opportunity appraisal for the Recovery filter, with a 67:13 date of March 20th, 2003. Do you see that?	05_21_18 Combo Jones V7_1.49

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	67:14 A. Yes.	
68:22 - 69:1	**Avino, Anthony 03-23-2017 (00:00:10)** 68:22 Q. Would you have wanted to know that Bard, 68:23 in 2003, was acknowledging internally that it lacked 68:24 a solid clinical history for the Recovery, and that 68:25 it had documented negative clinical experiences for 69:1 it?	05_21_18 Combo Jones V7_1.50
69:3 - 69:5	**Avino, Anthony 03-23-2017 (00:00:07)** 69:3 THE WITNESS: Just along the same lines of 69:4 wanting to know anything that's negative about 69:5 any device we use.	05_21_18 Combo Jones V7_1.51
71:20 - 71:21	**Avino, Anthony 03-23-2017 (00:00:09)** 71:20 Let's look at what's been marked 71:21 Exhibit 4021.	05_21_18 Combo Jones V7_1.52
72:1 - 72:10	**Avino, Anthony 03-23-2017 (00:00:29)** 72:1 Q. And if you go to the middle of the middle 72:2 paragraph of Janet Hudnall's February 26th, 2004, 72:3 e-mail to David Rauch, there's a sentence in there 72:4 that says: 72:5 "We know very little about the long-term 72:6 clinical performance of this device when we -- we 72:7 knew very little about the long-term clinical 72:8 performance of this device when we launched it. 72:9 After a year of commercialization, there are still 72:10 many questions that need to be answered."	05_21_18 Combo Jones V7_1.53
75:13 - 75:18	**Avino, Anthony 03-23-2017 (00:00:19)** 75:13 here you had a retrievable IVC 75:14 filter that was different than a permanent filter 75:15 which had been used for decades. Fair? 75:16 A. Yes. 75:17 Q. And that would raise different -- have a 75:18 different risk profile than the permanent IVC filter?	05_21_18 Combo Jones V7_1.56
75:21 - 76:4	**Avino, Anthony 03-23-2017 (00:00:20)** 75:21 THE WITNESS: Well, I guess no one -- no 75:22 one really knew for sure. I mean, there's some 75:23 changes in the design, but the assumption was 75:24 that it would still be -- still have a similar 75:25 risk/benefit ratio. 76:1 BY MR. COMBS: 76:2 Q. Right. And if the manufacturer doesn't	05_21_18 Combo Jones V7_1.57

Page/Line	Source	ID
	76:3 know, then putting it on the market is just a giant 76:4 clinical trial, right?	
76:7 - 76:7	**Avino, Anthony 03-23-2017 (00:00:01)** 76:7 THE WITNESS: To some degree.	05_21_18 Combo Jones V7_1.58
79:15 - 79:20	**Avino, Anthony 03-23-2017 (00:00:11)** 79:15 If there was a significant 79:16 difference between Recovery and Greenfield's Go?=nther 79:17 Tulip, Bird's Nest filter, SNF and VenaTech, and Bard 79:18 knew that in 2004, you would want to know that 79:19 information. Fair? 79:20 A. Yes, that is fair.	05_21_18 Combo Jones V7_1.59
79:21 - 80:1	**Avino, Anthony 03-23-2017 (00:00:12)** 79:21 (Exhibit 4023 was marked for identification.) 79:22 BY MR. COMBS: 79:23 Q. The next document is a Recovery filter arm 79:24 fracture remedial action plan of Bard on 79:25 September 2nd, 2004. Correct? 80:1 A. Yes.	05_21_18 Combo Jones V7_1.60 1133_FERRERA.1
81:10 - 81:24	**Avino, Anthony 03-23-2017 (00:00:40)** 81:10 Q. Turn to the right -- the 81:11 lower right corner of 884. 81:12 A. Okay. 81:13 Q. And there's a box up towards the top of 81:14 the page, and either the last or second-to-last 81:15 sentence there, in the top paragraph of the box, 81:16 says: "Recovery filter fracture rates exceed the 81:17 rates reported by other manufacturers in the MAUDE 81:18 database." 81:19 Do you see that? 81:20 A. Yes. 81:21 Q. Is that information you would have wanted 81:22 to know in 2004? 81:23 A. Yes, if there's a higher fracture rate, 81:24 yes.	05_21_18 Combo Jones V7_1.61 clear 1133_FERRERA.25.1 clear
82:9 - 82:13	**Avino, Anthony 03-23-2017 (00:00:10)** 82:9 Q. That's marked 4024. 82:10 A. Okay. 82:11 Q. And this is a Health Hazard Evaluation, 82:12 December 17th, 2004, Bard? 82:13 A. Agreed.	05_21_18 Combo Jones V7_1.62

Page/Line	Source	ID
82:14 - 82:15	**Avino, Anthony 03-23-2017 (00:00:10)** 82:14 Q. And on the second page, under number 2, A, 82:15 see there, it says: "Reports of	05_21_18 Combo Jones V7_1.63
82:15 - 82:24	**Avino, Anthony 03-23-2017 (00:00:24)** 82:15 filter 82:16 migration (movement), IVC perforation, and filter 82:17 fracture associated with Recovery filter were seen in 82:18 the MAUDE database at reporting rates that were 4.6, 82:19 4.4, 4.1 and 5.3 higher, respectively, than reporting 82:20 rates for all other filters." 82:21 Is that information you wanted, that Bard 82:22 knew in December 2004, and that would have been 82:23 important to you? 82:24 A. Yes.	05_21_18 Combo Jones V7_1.64
84:15 - 84:21	**Avino, Anthony 03-23-2017 (00:00:21)** 84:15 Would you have expected Bard in 2008 to still have a 84:16 lack of thorough understanding of the dynamics of the 84:17 caval anatomy? 84:18 A. Not really. I mean, are we still -- 84:19 everyone's still trying to figure out the anatomy of 84:20 the -- all the devices and the anatomy of what we put 84:21 it in, arteries in motion.	05_21_18 Combo Jones V7_1.65
84:25 - 85:3	**Avino, Anthony 03-23-2017 (00:00:12)** 84:25 Q. Is that information that would have been 85:1 important for you to know, that Bard in 2008 was 85:2 still assessing internally that it didn't have a 85:3 thorough understanding of caval anatomy?	05_21_18 Combo Jones V7_1.66
85:9 - 85:12	**Avino, Anthony 03-23-2017 (00:00:08)** 85:9 I don't think anyone 85:10 has great understanding, especially back then, 85:11 of the dynamics of caval anatomy, because it's 85:12 so complicated.	05_21_18 Combo Jones V7_1.67
89:14 - 89:22	**Avino, Anthony 03-23-2017 (00:00:17)** 89:14 Q. the fracture rates they're 89:15 reporting here aren't vague. True? 89:16 A. Correct. You're right. 89:17 Q. And is that information that would have 89:18 been important for you in deciding to use Bard IVC 89:19 filters? 89:20 A. Yes. All of the fracture information rate	05_21_18 Combo Jones V7_1.97

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	89:21 is something that was important to consider in the 89:22 decision.	
90:12 - 90:16	**Avino, Anthony 03-23-2017 (00:00:14)** 90:12 Is that information 90:13 that would have been important to you, to know that 90:14 the medical director for Bard in 2005 was questioning 90:15 why Bard was pushing the G2 as a permanent filter 90:16 when they already had the SNF one?	05_21_18 Combo Jones V7_1.98
90:19 - 90:22	**Avino, Anthony 03-23-2017 (00:00:10)** 90:19 THE WITNESS: You know, again, all 90:20 information is helpful, if there's -- if it is 90:21 information regarding concern about one filter 90:22 being better than the other.	05_21_18 Combo Jones V7_1.99
90:24 - 91:7	**Avino, Anthony 03-23-2017 (00:00:25)** 90:24 Q. And certainly, Doris could have received 90:25 an SNF or another permanent filter instead of an 91:1 Eclipse or other retrievable filter. True? 91:2 A. Well, not necessarily. Like I said in the 91:3 op note at the beginning, we still wanted -- there 91:4 was a -- there was a -- there was a reason I 91:5 mentioned for putting the retrievable filter in, just 91:6 to have the option to then take it out. So they're 91:7 not completely equivalent.	05_21_18 Combo Jones V7_1.71
91:8 - 91:10	**Avino, Anthony 03-23-2017 (00:00:07)** 91:8 Q. But the option for retrievability 91:9 is balanced against the risk of using a retrievable 91:10 versus a permanent filter; right?	05_21_18 Combo Jones V7_1.72
91:12 - 91:22	**Avino, Anthony 03-23-2017 (00:00:22)** 91:12 THE WITNESS: Right. There's the risk of 91:13 using the retrievable one when we know that the 91:14 Simon Nitinol was a good filter, and then 91:15 there's the risks of putting the Simon Nitinol 91:16 in, but you can't ever take it out. 91:17 BY MR. COMBS: 91:18 Q. Right. And knowing that the medical 91:19 director of Bard, as far back as 2005, was 91:20 questioning why people weren't using the Simon 91:21 Nitinol filter more, that would be important 91:22 information to that calculation?	05_21_18 Combo Jones V7_1.73
91:25 - 92:1	**Avino, Anthony 03-23-2017 (00:00:04)**	05_21_18 Combo Jones V7_1.74

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	91:25 THE WITNESS: It's all additional pieces 92:1 of information, sure.	
93:21 - 93:25	**Avino, Anthony 03-23-2017 (00:00:14)** 93:21 Do you know what Bard did at any time to 93:22 investigate reports of events with any of its 93:23 filters? 93:24 A. No, 93:25 they did.	05_21_18 Combo Jones V7_1.75
94:15 - 94:23	**Avino, Anthony 03-23-2017 (00:00:23)** 94:15 Q. Do you know whether any manufacturer whose 94:16 filters you have used has a filter that never 94:17 fractures? 94:18 A. No, I'm not aware of any. 94:19 Q. Do you know of any of those manufacturers 94:20 that have filters that fracture that have found a 94:21 root cause for why a filter fractures in a patient 94:22 and doesn't fracture in another patient? 94:23 A. No.	05_21_18 Combo Jones V7_1.76
104:5 - 104:18	**Avino, Anthony 03-23-2017 (00:00:42)** 104:5 Q. What was your -- what was your general 104:6 experience with the Eclipse filter that you used in 104:7 Ms. Jones? 104:8 A. It was a good experience. I never had a 104:9 bad experience with them. I didn't -- this -- I 104:10 didn't have any fractures that I knew about until 104:11 this one. 104:12 Q. Okay. You were -- you have been asked a 104:13 lot of questions about information that doctors want 104:14 to know. And early in the deposition, you were asked 104:15 a question about getting all the information about a 104:16 product. Do you think you ever have all the 104:17 information about a product? 104:18 A. No.	05_21_18 Combo Jones V7_1.77
104:21 - 105:9	**Avino, Anthony 03-23-2017 (00:00:30)** 104:21 Q. Any device that you've placed, do you have 104:22 all the information? 104:23 A. No. 104:24 Q. And you also testified a little bit ago 104:25 about how the clinical experience with a device adds 105:1 to the body of knowledge, correct?	05_21_18 Combo Jones V7_1.78

Page/Line	Source	ID
	105:2 A. Correct. 105:3 Q. And that whenever a device comes on the 105:4 market, you never know everything that you may find 105:5 out about the device as years go on. True? 105:6 A. True. 105:7 Q. And that's true of everybody's devices, 105:8 true? 105:9 A. True.	
105:10 - 105:25	**Avino, Anthony 03-23-2017 (00:00:48)** 105:10 Q. You were talking about going to 105:11 presentations about devices, including filters, and I 105:12 assume those are, like, medical continuing 105:13 education-type presentations; is that right? 105:14 A. Yes. 105:15 Q. All right. And you said that -- that 105:16 there were people who were chosen to make 105:17 presentations at these groups. Were those chosen by 105:18 the medical community? How were people chosen to 105:19 present at those meetings? 105:20 A. By the medical community. 105:21 Q. And was the -- was the criteria that those 105:22 people had a certain expertise or deep clinical 105:23 knowledge of those devices, and that's why they were 105:24 speaking? 105:25 A. Yes.	05_21_18 Combo Jones V7_1.79
106:9 - 106:13	**Avino, Anthony 03-23-2017 (00:00:11)** 106:9 Q. Did you feel like at those events, you as 106:10 an attending doctor were able to ask whatever 106:11 questions you wanted, both of the presenters and the 106:12 people around you, about those devices? 106:13 A. Yes.	05_21_18 Combo Jones V7_1.95
106:14 - 107:13	**Avino, Anthony 03-23-2017 (00:00:55)** 106:14 Q. You were asked about the consent process 106:15 for Mrs. Jones. I want to go back to that a minute. 106:16 And you pointed out that her husband had signed the 106:17 consent. 106:18 A. Yes. 106:19 Q. But then within the consent itself, it 106:20 says -- "long discussion with her," I think, is what 106:21 it says, correct?	05_21_18 Combo Jones V7_1.80

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	106:22 A. Right. 106:23 Q. Do you have a recollection sitting here 106:24 today, one way or the other, whether she was a part 106:25 of the conversation or not? 107:1 A. I do not. 107:2 Q. So do you have any way to know whether she 107:3 had an understanding of what you were telling her 107:4 about the filter, as you sit here today? 107:5 A. No. Only to go by my note, which, you 107:6 know, is not a perfect -- not a very detailed 107:7 description of that. 107:8 Q. Do you typically try to make sure that 107:9 either the patient, or if the patient is unable to 107:10 understand it, the family member has a full 107:11 opportunity to ask questions and to get an 107:12 understanding of the procedure and the device? 107:13 A. Absolutely.	
108:18 - 108:22	**Avino, Anthony 03-23-2017 (00:00:16)** 108:18 Q. do you see publications, even 108:19 in -- as recently as 2016, where the authors are 108:20 commenting about a lack of really deep understanding, 108:21 even today, of caval anatomy and how it and how the 108:22 vena cava operates?	05_21_18 Combo Jones V7_1.81
108:24 - 109:4	**Avino, Anthony 03-23-2017 (00:00:18)** 108:24 THE WITNESS: Yes. You know, most studies 108:25 end with a qualifier of "more study, more 109:1 research is necessary." You know, it's just -- 109:2 it's part of scientific research to understand 109:3 the limitations of what's known and what's not 109:4 known.	05_21_18 Combo Jones V7_1.82
109:17 - 109:18	**Avino, Anthony 03-23-2017 (00:00:04)** 109:17 Q. Now, if we could go to the records again 109:18 for Mrs. Jones,	05_21_18 Combo Jones V7_1.83
110:7 - 111:14	**Avino, Anthony 03-23-2017 (00:01:34)** 110:7 Q. And it's 4017, we've called that exhibit. 110:8 Sorry. 110:9 A. Yes. 110:10 Q. All right. Sorry. So can you describe 110:11 for me what is meant by -- under the indications, 110:12 where it says. "The patient had a long history of	05_21_18 Combo Jones V7_1.84 4401_IMPLANT.1.3

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	110:13 high DVT." What does that mean?	
	110:14 A. Well, it may be a typo, or I may have been	
	110:15 saying -- I wouldn't really use the word "high" so	clear
	110:16 I'm not completely sure. Maybe -- I don't know what	
	110:17 sounds just like it.	
	110:18 Q. That may have been a transcription issue?	
	110:19 A. Yeah, because "high DVT" is not -- that's	
	110:20 a general laymen's term I wouldn't have used in	
	110:21 there.	
	110:22 Q. So we can take that out, and just call it	
	110:23 a long-standing history of DVT?	
	110:24 A. Yeah, recurrent, or -- you know, that was	
	110:25 my understanding, she had had recurrent, prior,	
	111:1 multiple ...	
	111:2 Q. Okay. And then it goes on to say "...and	4401_IMPLANT.1.4
	111:3 now has afferent loop syndrome, scheduled for	
	111:4 upcoming surgery."	
	111:5 And then again, "with recurrent DVT."	
	111:6 What is afferent loop syndrome?	
	111:7 A. Something I used to know a whole lot more	clear
	111:8 about than I do now.	
	111:9 Q. Okay.	
	111:10 A. It's a gastrointestinal disorder that	
	111:11 causes -- sometimes it's surgical; it's related to	
	111:12 the small bowel and reflux and irritation, bleeding.	
	111:13 It's a complicated syndrome that, you know, has,	
	111:14 like, textbooks written about it.	
111:25 - 112:17	**Avino, Anthony 03-23-2017 (00:00:56)**	05_21_18 Combo Jones V7_1.85
	111:25 Q. Are these -- are these documents that you	
	112:1 would have had access to?	
	112:2 A. Yes.	
	112:3 Q. And may have reviewed on this patient when	
	112:4 you did the consult?	
	112:5 A. Yes.	
	112:6 Q. All right. So if you would look for me	
	112:7 at -- under "Assessment and Plan," it lists there,	
	112:8 into the next page, several conditions for Ms. Jones.	
	112:9 And I would -- wanted to ask you whether you can tell	
	112:10 from this whether these were presenting conditions or	
	112:11 prior conditions, starting with severe anemia.	

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	112:12 A. I would say that's a presenting symptom of 112:13 severe anemia. 112:14 Q. Then it talks about history of peptic 112:15 ulcer disease. That's requiring the surgery she's 112:16 coming in for; is that right? 112:17 A. Yes.	
113:2 - 113:12	**Avino, Anthony 03-23-2017 (00:00:30)** 113:2 Q. It goes on to say: "Makes a GI bill -- 113:3 makes a GI bleed most likely source of current 113:4 anemia." 113:5 Do you see that? 113:6 A. Yes. 113:7 Q. All right. Is there any -- is there any 113:8 relevance to the condition that we have just read 113:9 under 1 to a decision to give her an IVC filter or 113:10 not? 113:11 A. Yes. 113:12 Q. And what's the relevance?	05_21_18 Combo Jones V7_1.86
113:14 - 114:16	**Avino, Anthony 03-23-2017 (00:01:28)** 113:14 And 113:15 the other is her severe anemia and her high risk for 113:16 bleeding -- and high risk for recurrent bleeding. So 113:17 all -- you know, all significant indication -- 113:18 significant risks for complications from her DVTs. 113:19 Q. And if she did have a bleed, would use of 113:20 anticoagulants in a patient like that perhaps be 113:21 contraindicated for a period of time? 113:22 A. Yes. 113:23 Q. Would that be another reason why the IVC 113:24 filter might be a good treatment option for her? 113:25 A. Yes. 114:1 Q. Now, also noted that her date of birth -- 114:2 it's at the top of the page you're on: 2-10-65. So 114:3 in 2010, when she was getting this treatment, she was 114:4 a relatively young woman; would you agree? 114:5 A. I was born the same year, so I definitely 114:6 agree. 114:7 Q. And would the fact that she was a 114:8 relatively young woman also be relevant to a decision 114:9 to use a retrievable IVC filter in her case?	05_21_18 Combo Jones V7_1.96

Page/Line	Source	ID
	114:10 A. Yes. 114:11 Q. And why is that? 114:12 A. Because no one knows the long-term 114:13 complications of leaving them in for decades. And 114:14 everyone is -- has some concern about occlusion. And 114:15 if you have an occlusion, then you want to be able to 114:16 do lysis and take the filter out.	
115:4 - 115:12	**Avino, Anthony 03-23-2017 (00:00:19)** 115:4 Q. And I think the last time you 115:5 reported on the filter in Ms. Jones was on the date 115:6 of implant, and your records indicate that the filter 115:7 was in good position. Correct? 115:8 A. Correct. 115:9 Q. And that she did not have any 115:10 complications from the implant procedure; is that 115:11 true? 115:12 A. Yes.	05_21_18 Combo Jones V7_1.87
119:16 - 119:23	**Avino, Anthony 03-23-2017 (00:00:15)** 119:16 Did you ever hear of fractures occurring 119:17 in other non-Bard filters? 119:18 A. Yes. 119:19 Q. And then I was going to ask you about 119:20 Eclipse. Did you ever experience a fracture other 119:21 than this one that you know Ms. Jones had in an 119:22 Eclipse? 119:23 A. No.	05_21_18 Combo Jones V7_1.88
119:24 - 120:24	**Avino, Anthony 03-23-2017 (00:01:07)** 119:24 Q. With respect to your experience of 119:25 retrievability of the various Bard filters, what's 120:1 been your general experience with retrievability? 120:2 A. They're easily retrievable. 120:3 Q. Has that changed much, iteration by 120:4 iteration? 120:5 A. Well, just like all the other devices, 120:6 they just keep getting easier. 120:7 Q. Okay. Do you think that is a product of 120:8 the -- the evolution of the filter, or the evolution 120:9 of the doctor? 120:10 A. I was just thinking that. I would like to 120:11 think it was the evolution of the doctor. At some	05_21_18 Combo Jones V7_1.89

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	120:12 point I'll reach a peak and get worse, and hopefully 120:13 technology will keep us looking good. 120:14 Q. But you haven't peaked yet? 120:15 A. No, I don't think I've peaked yet. 120:16 Q. Okay. 120:17 A. No, I do -- I think that along with other 120:18 medical devices, I think the filters have only gotten 120:19 better and easier to -- they've always been easy to 120:20 deploy, but they're definitely easier to retrieve. 120:21 Q. Do you recall any time that you ever asked 120:22 Bard to give you specific information about a device 120:23 of theirs that they did not respond to you? 120:24 A. No.	
124:17 - 124:23	**Avino, Anthony 03-23-2017 (00:00:17)** 124:17 Q. And, in fact, Eclipse is a G2 filter with 124:18 electropolishing as the only modification. Do you 124:19 know what electropolishing is? 124:20 A. No, I just know -- I've heard the term, 124:21 that it's another surface that was supposed to be 124:22 stronger and better, but I don't know the physics of 124:23 it.	05_21_18 Combo Jones V7_1.90

Plaintiff Designations = 00:12:20
Defense Designations = 00:26:31
Plaintiff and Defense Designations = 00:04:48
Total Time = 00:43:39

Documents Shown
1133_FERRERA
4401_IMPLANT

Exhibit C

Designation Run Report

Chodos 08-05-17 Jones Trial Designation V7

Chodos, David 08-05-2017

Plaintiffs Designations 00:08:18

Defense Designations 00:21:50

Plaintiffs and Defense Designations 00:02:19

Total Time 00:32:27

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5:8 - 5:10	**Chodos, David 08-05-2017 (00:00:04)** 5:8 Q. Would you state your full name for the 5:9 record, please. 5:10 A. David Jason Chodos.	05_21_18 Jones Combo V7.1
11:9 - 11:12	**Chodos, David 08-05-2017 (00:00:07)** 11:9 Q. are you board certified in internal 11:10 medicine? 11:11 A. I am board eligible. I'll be taking my 11:12 board exams in the next two weeks.	05_21_18 Jones Combo V7.2
12:2 - 12:5	**Chodos, David 08-05-2017 (00:00:08)** 12:2 Now, infectious disease: Is that a 12:3 subspecialty of internal medicine? 12:4 A. Yes, infectious disease is one of many 12:5 subspecialties from internal medicine.	05_21_18 Jones Combo V7.3
12:23 - 12:25	**Chodos, David 08-05-2017 (00:00:05)** 12:23 Q. In the area of internal 12:24 medicine, do you diagnose conditions and diseases? 12:25 A. Yes, sir.	05_21_18 Jones Combo V7.4
13:9 - 13:11	**Chodos, David 08-05-2017 (00:00:05)** 13:9 Q. And the art of diagnosis, does that 13:10 involve what's known as a differential diagnosis? 13:11 A. Absolutely.	05_21_18 Jones Combo V7.5
19:5 - 19:12	**Chodos, David 08-05-2017 (00:00:22)** 19:5 Q. We're here to talk about an individual who 19:6 became a patient of yours, Doris Jones. You reviewed 19:7 records before you got here today? 19:8 A. Briefly, yes, sir. 19:9 Q. And did you actually generate some of the 19:10 records in Doris Jones' matter? 19:11 A. Yes, sir. I have generated some of the 19:12 records in her medical chart from Memorial.	05_21_18 Jones Combo V7.8
22:18 - 22:21	**Chodos, David 08-05-2017 (00:00:13)** 22:18 Q. Let's talk about Doris Jones. When did 22:19 she become a patient of yours? 22:20 A. Doris Jones presented to Memorial's 22:21 emergency department I believe on April 22nd, 2015.	05_21_18 Jones Combo V7.9
22:25 - 23:10	**Chodos, David 08-05-2017 (00:00:28)** 22:25 Q. How was it that you became involved with 23:1 Doris' care? 23:2 A. The emergency department physicians at	05_21_18 Jones Combo V7.10

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	23:3 Memorial Hospital would triage patients, which is 23:4 basically how they assess risk and what is going on 23:5 with the patient. Following their assessment and 23:6 risk of a patient, if they believe that a parent -- a 23:7 patient merits admission to the hospital, they will 23:8 usually call a physician, who will admit the patient 23:9 to the hospital based on what they think the 23:10 admission diagnosis is.	
24:4 - 24:10	**Chodos, David 08-05-2017 (00:00:16)** 24:4 Q. What was your role? 24:5 A. My role was the intern on the team with 24:6 Dr. Jaime Sanchez. At that point, after he took a 24:7 handoff from the emergency department physician, he 24:8 discussed a bit of the case with me. We looked at 24:9 the chart together, and he asked me to go see the 24:10 patient in the emergency department.	05_21_18 Jones Combo V7.11
27:21 - 28:10	**Chodos, David 08-05-2017 (00:00:40)** 27:21 Q. So when you started with the history 27:22 process, did you ask and did Doris tell you what 27:23 problems she was having that brought her to the 27:24 hospital? 27:25 A. Yes, sir. 28:1 Q. What did she tell you? 28:2 A. The complaints that she presented with 28:3 were specifically lightheadedness and arm pain. And 28:4 that would be bilateral arm pain. 28:5 Q. And did she tell you when that onset 28:6 started? 28:7 A. Yes, she stated that the symptoms 28:8 developed on April 21st, so that would be 28:9 approximately a day prior. And these symptoms came 28:10 on when she was at her place of employment, cleaning.	05_21_18 Jones Combo V7.14
29:3 - 29:17	**Chodos, David 08-05-2017 (00:00:41)** 29:3 Q. What did you learn from Doris? 29:4 A. Oh, that she had some symptoms that were 29:5 basically a little more atypical to what I would have 29:6 expected for any one of those presenting symptoms. 29:7 In addition to that, as I said, I also take a 29:8 thorough past medical history, learning that she has 29:9 a history of high blood pressure, as well as deep	05_21_18 Jones Combo V7.15

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	29:10 vein thrombosis, as well as peptic ulcer disease. 29:11 I also scoured her surgical history and 29:12 was able to obtain some information about her past 29:13 surgeries, which included surgery for peptic ulcer 29:14 disease -- actually three of them -- with open 29:15 surgical intervention and procedures, as well as a 29:16 vagotomy, to help reduce what I could assume would be 29:17 the severity of her peptic ulcer disease.	
34:14 - 34:16	**Chodos, David 08-05-2017 (00:00:03)** 34:14 Q. Now, was there any imaging that you 34:15 reviewed? 34:16 A. Yes, sir.	05_21_18 Jones Combo V7.16
34:17 - 34:19	**Chodos, David 08-05-2017 (00:00:05)** 34:17 I was able to 34:18 review a chest radiograph, which is an x-ray film of 34:19 the chest.	05_21_18 Jones Combo V7.17
35:20 - 35:22	**Chodos, David 08-05-2017 (00:00:10)** 35:20 Q. And then you also looked at a CT imaging 35:21 study as well. Is that correct? 35:22 A. Yes, sir.	05_21_18 Jones Combo V7.18
36:23 - 36:25	**Chodos, David 08-05-2017 (00:00:04)** 36:23 Q. And if you would, tell us about the x-ray 36:24 first. 36:25 A. Okay.	05_21_18 Jones Combo V7.20
37:1 - 37:2	**Chodos, David 08-05-2017 (00:00:01)** 37:1 Q. What was in -- what impressed you about 37:2 it?	05_21_18 Jones Combo V7.21
37:4 - 37:9	**Chodos, David 08-05-2017 (00:00:19)** 37:4 THE WITNESS: The x-ray report, as well as 37:5 the imaging, which I personally reviewed on a 37:6 computer station prior to seeing the patient, 37:7 demonstrated a metallic object in the right 37:8 hilum, seen on both PA and lateral projections 37:9 of the chest radiograph.	05_21_18 Jones Combo V7.22
39:12 - 40:13	**Chodos, David 08-05-2017 (00:01:15)** 39:12 what is the right -- did you call 39:13 it the "hilum"? 39:14 A. Yes, sir, the hilum. Loosely, without 39:15 getting into too much medical jargon, it describes 39:16 the portion of a patient's right side of the chest	05_21_18 Jones Combo V7.24

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39:17 that exists just next to what you would see on the
39:18 heart, heart being on the left side. Then you have
39:19 what they call the mediastinum, which is the middle.
39:20 The right hilum would be basically just that right
39:21 section, just next to the mediastinum, where you have
39:22 a good density of vasculature. There's lung behind
39:23 all this. It's an area just adjacent on the
39:24 right-hand side.
39:25 Q. What is the pulmonary artery?
40:1 A. So the pulmonary artery is a branch that
40:2 feeds from the right ventricle to the -- basically to
40:3 the lungs themselves. The pulmonary arteries are the
40:4 transporting tubes, basically, for blood that goes
40:5 from the heart to the lungs. And then you'll have
40:6 the pulmonary veins after the lungs, which is where
40:7 the blood is oxygenated, and then brings it back to
40:8 the left side of the heart, where blood can then be
40:9 functioned and purposed to be distributed to the rest
40:10 of the body.
40:11 Q. So does the pulmonary artery take blood
40:12 that is lacking in oxygen and circulate it through
40:13 the lungs?

40:15 - 40:17 **Chodos, David 08-05-2017 (00:00:07)** 05_21_18 Jones Combo V7.25

40:15 THE WITNESS: Yes, sir. Pulmonary
40:16 arteries will take deoxygenated blood and
40:17 circulate them to the lungs.

41:21 - 42:4 **Chodos, David 08-05-2017 (00:00:30)** 05_21_18 Jones Combo V7.26

41:21 Q. And talk to us and tell us about the CT
41:22 angiogram. What information did that provide you?
41:23 A. The CT angiogram, again, characterize a
41:24 metallic density. This time it was able to show us a
41:25 little bit better exactly where it was. Instead of
42:1 being as vague as the right hilum, we now had the
42:2 metallic density in the right middle lobe pulmonary
42:3 artery. And -- and that's pretty much what it
42:4 showed.

43:6 - 43:13 **Chodos, David 08-05-2017 (00:00:20)** 05_21_18 Jones Combo V7.28

43:6 Q. Did you review Dr. Helmly's impression of
43:7 the CT angiogram before seeing Doris?
43:8 A. Yes, sir, I did.

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	43:9 Q. And what was that impression? 43:10 A. That impression was, to quote page 136, 43:11 was "metallic density within the right middle lobe 43:12 pulmonary artery. This likely represents a foreign 43:13 body, possibly a limb of the IVC filter."	
44:12 - 44:22	**Chodos, David 08-05-2017 (00:00:38)** 44:12 Q. Did the CT angiogram, including the 44:13 impressions, provide you any information that helped 44:14 you understand the complaints that Doris had 44:15 presented to you with? 44:16 A. The CT -- the CT angiogram absolutely 44:17 helped us characterize her complaints a little bit 44:18 further. Again, it's hard to say, because in all of 44:19 my medical experience, albeit limited, I have never 44:20 seen a metallic embolism in the pulmonary 44:21 vasculature. But this being not normal can 44:22 absolutely explain her presenting symptoms.	05_21_18 Jones Combo V7.29
44:23 - 45:8	**Chodos, David 08-05-2017 (00:00:27)** 44:23 However, I would like to note that despite 44:24 this, we still continued to work the patient up for 44:25 very common presenting things, like a heart attack, 45:1 which she -- after a day of our workup showed that 45:2 she did not actually have a heart attack. And these 45:3 imaging studies also confirmed that we were not 45:4 dealing with an aortic dissection or a pneumothorax, 45:5 other very concerning things that were on our 45:6 differential, very near the top of the differential, 45:7 that we needed to be sure the patient wasn't 45:8 presenting with.	05_21_18 Jones Combo V7.30
45:24 - 46:10	**Chodos, David 08-05-2017 (00:00:31)** 45:24 Q. And as I understand it, in addition to the 45:25 metallic foreign body that was in the pulmonary 46:1 artery, there were still other conditions on your 46:2 differential, which included a pneumothorax? 46:3 A. Yes, sir. 46:4 Q. And -- and a dissection of the aorta? 46:5 A. Yes, sir. 46:6 Q. And then also a heart attack? 46:7 A. Yes, sir. Those are three examples of 46:8 several things that were on the differential.	05_21_18 Jones Combo V7.31

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	46:9 Q. Did you eventually rule those three out? 46:10 A. Yes, sir.	
46:10 - 47:1	**Chodos, David 08-05-2017 (00:00:45)** 46:10 A. The heart attack, as I 46:11 mentioned a little earlier, was ruled out with a 46:12 combination of serial EKGs and serial cardiac 46:13 enzymes, cardiac enzymes specifically being 46:14 troponin I, which is a very sensitive blood marker 46:15 assay for cardiac damage. In addition to that, the 46:16 EKG did not demonstrate anything on repeat 46:17 examination that was concerning for a heart attack. 46:18 In addition to that, to rule out 46:19 pneumothorax, the chest x-ray as well as the CT scan 46:20 did not demonstrate any evidence of pneumothorax, 46:21 which would be very obvious on either -- obvious on 46:22 the chest x-ray, but very obvious on a CT scan. 46:23 And then the aortic dissection would 46:24 again -- can be suggested by a chest x-ray, but 46:25 should be very well elucidated on a CT scan, 47:1 especially with contrast, such as this.	05_21_18 Jones Combo V7.32
47:16 - 48:2	**Chodos, David 08-05-2017 (00:00:35)** 47:16 Q. So what was your next step? Did you order 47:17 additional tests, or what did you order? 47:18 A. So having the tests available ahead of us, 47:19 we felt that our next best step, given the fact that 47:20 we saw a foreign metallic density in an artery where 47:21 a foreign metallic density shouldn't be, regardless 47:22 of what other prior interventions this patient has 47:23 had, we felt it best to obtain counsel from an expert 47:24 in the field of vasculature, anatomy, and radiology, 47:25 someone who could possibly go in and retrieve the 48:1 density and remove it, as we felt that its presence 48:2 wasn't best suited for the patient.	05_21_18 Jones Combo V7.33
48:5 - 48:7	**Chodos, David 08-05-2017 (00:00:05)** 48:5 Q. why is that? Why wouldn't that be 48:6 best suited for a patient? Can you elaborate, 48:7 please?	05_21_18 Jones Combo V7.34
48:11 - 48:12	**Chodos, David 08-05-2017 (00:00:03)** 48:11 Q. you're talking about the 48:12 metallic foreign body in the pulmonary artery, right?	05_21_18 Jones Combo V7.35

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48:14 - 49:24 **Chodos, David 08-05-2017 (00:01:29)** 05_21_18 Jones Combo V7.36

48:14 THE WITNESS: Yes, sir.
48:15 BY MR. O'CONNOR:
48:16 Q. Why was that a concern?
48:17 A. Well, just -- just discussing normal
48:18 anatomy, in a normal human being, there shouldn't be
48:19 any metallic object anywhere in any of our
48:20 vasculature. Once you start talking about higher
48:21 risk vasculature, "higher risk" being vasculature
48:22 around organs, or in areas where bleeding can be a
48:23 big concern, a metal object in a vessel that feeds
48:24 from the heart, so a possible high-pressure -- not
48:25 "high pressure"; that's not a -- that's not a correct
49:1 term, because those vessels aren't very
49:2 high-pressure.
49:3 But a highly perfused -- that's a much
49:4 better way of phrasing that -- a highly perfused
49:5 vessel is a very concerning finding. And metal
49:6 shouldn't be there.
49:7 Q. When you talk about high-risk vasculature,
49:8 is the pulmonary artery -- does it fall into that
49:9 class?
49:10 A. Again, I -- I'd have to look at a medical
49:11 textbook to say exactly, but I would absolutely, in
49:12 my experience, consider that a high-risk piece of
49:13 vasculature. Again, because the pulmonary arteries
49:14 see a good volume of blood from the heart to the --
49:15 circulated to the lungs.
49:16 And again, if you rupture a pulmonary
49:17 artery, you're again in the thoracic cavity of
49:18 someone's body, the thoracic cavity being the chest
49:19 cavity, where there is not much free space to fill up
49:20 with blood; and the free space that is available to
49:21 fill up with blood would be the area around the
49:22 heart, or the lungs themselves, both of which would
49:23 be not very good areas for blood to be outside of
49:24 blood vessels.

56:10 - 56:12 **Chodos, David 08-05-2017 (00:00:05)** 05_21_18 Jones Combo V7.38

56:10 did you conduct an examination?
56:11 A. Yes, sir, I did conduct an examination.

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	56:12 Q. Can you tell us about that?	
56:25 - 57:11	**Chodos, David 08-05-2017 (00:00:32)** 56:25 A. So my physical examination, as most will 57:1 begin with, is a review of the vital signs, which are 57:2 usually taken by a nursing member, not usually by 57:3 myself. And that showed a blood pressure of 180 over 57:4 102, which is definitely elevated; a heart rate of 57:5 82, which is normal; respiratory rate of 18, which is 57:6 also normal; and oxygenation saturation of 57:7 100 percent on room air, which is normal. 57:8 Temperature was 98.3 degrees; this was also normal. 57:9 Then a general, basically, assessment of 57:10 the patient. She was not appearing in any distress, 57:11 and she was sitting up in bed during our interview.	05_21_18 Jones Combo V7.39
60:2 - 60:9	**Chodos, David 08-05-2017 (00:00:21)** 60:2 Q. What was your assessment in this case, 60:3 after you have taken the history, reviewed the data, 60:4 which included the imaging, and performed your 60:5 physical examination of Doris Jones? 60:6 A. So my assessment, as I read from the page 60:7 here, was "foreign body embolism: right middle lobe 60:8 pulmonary artery, probable inferior vena cava filter 60:9 source."	05_21_18 Jones Combo V7.40
61:8 - 61:21	**Chodos, David 08-05-2017 (00:00:44)** 61:8 Q. Why is there a concern when there is a 61:9 foreign embolism in the pulmonary vasculature? 61:10 A. As we mentioned a little earlier, the 61:11 pulmonary vasculature being in a more concerning 61:12 area -- specifically, so close to the heart -- and 61:13 receiving such a high flow of blood from the heart, 61:14 would make it concerning. Specifically, you would 61:15 not want to end up with any sort of shear on any of 61:16 these vessels, because if they were to start 61:17 bleeding, there could be significant consequences and 61:18 sometimes not illuminated immediately. Sometimes 61:19 they can occur late. But you would not want to end 61:20 up with blood anywhere in the chest cavity, and you 61:21 would not want to have that amount of flow.	05_21_18 Jones Combo V7.41
62:12 - 62:14	**Chodos, David 08-05-2017 (00:00:07)** 62:12 Q. with your assessment, did you	05_21_18 Jones Combo V7.42

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	62:13 arrive at a plan for care of this patient?	
	62:14 A. Yes, sir.	
63:10 - 63:11	**Chodos, David 08-05-2017 (00:00:03)**	05_21_18 Jones Combo V7.43
	63:10 What	
	63:11 was your plan for the assessments that you made?	
63:16 - 63:23	**Chodos, David 08-05-2017 (00:00:19)**	05_21_18 Jones Combo V7.44
	63:16 A. So after my assessment, and I subtype A	
	63:17 here, or as -- it appears that it was formatted as	
	63:18 subtype A. Plan will be: Patient to angio suite	
	63:19 with interventional radiology for IVC filter removal	
	63:20 tomorrow.	
	63:21 Q. And "tomorrow" is --	
	63:22 A. This was dated on the 22nd, so this would	
	63:23 assume the 23rd.	
64:10 - 64:21	**Chodos, David 08-05-2017 (00:00:28)**	05_21_18 Jones Combo V7.45
	64:10 Moving forward, "The patient would	
	64:11 benefit -- may benefit from anticoagulation versus	
	64:12 antiplatelet agents, as portion of the IVC filter	
	64:13 will be left in the right pulmonary artery."	
	64:14 This portion was garnished after	
	64:15 discussion with the subspecialists, the	
	64:16 interventional radiologists, who were going to be	
	64:17 retrieving the -- the filter, and were discussing	
	64:18 about the portion that was left in the pulmonary	
	64:19 artery that would probably not be amenable to	
	64:20 retrieval.	
	64:21 Q. Why?	
64:23 - 65:1	**Chodos, David 08-05-2017 (00:00:06)**	05_21_18 Jones Combo V7.46
	64:23 THE WITNESS: To my knowledge -- and	
	64:24 again, I am not the expert in this field -- to	
	64:25 my knowledge, it was in a high-risk area for	
	65:1 retrieval.	
65:3 - 65:3	**Chodos, David 08-05-2017 (00:00:01)**	05_21_18 Jones Combo V7.47
	65:3 Q. Is that what you were told?	
65:5 - 65:11	**Chodos, David 08-05-2017 (00:00:13)**	05_21_18 Jones Combo V7.48
	65:5 THE WITNESS: That is what I was told.	
	65:6 BY MR. O'CONNOR:	
	65:7 Q. By who?	
	65:8 A. I believe the interventional radiology	
	65:9 team. I cannot specify exactly which physician, but	

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	65:10 if I had to look back to the notes, it looks like it 65:11 would be Dr. Nelson who was seeing the patient.	
67:11 - 67:14	**Chodos, David 08-05-2017 (00:00:12)** 67:11 Q. so in terms of the filter piece that 67:12 was seen in the pulmonary artery, can you tell us 67:13 what you determined and put in the discharge summary 67:14 relating to that?	05_21_18 Jones Combo V7.49
67:20 - 68:1	**Chodos, David 08-05-2017 (00:00:17)** 67:20 "The portion that was lodged in the right 67:21 pulmonary artery, however remained behind as 67:22 that it was in a dangerous area and was not 67:23 suitable for removal. Per interventional 67:24 radiology recommendations as well as 67:25 recommendations of Dr. Morris, the patient was 68:1 not placed on anticoagulation upon discharge."	05_21_18 Jones Combo V7.50
69:20 - 69:23	**Chodos, David 08-05-2017 (00:00:15)** 69:20 Q. Now, during the course of the 69:21 hospitalization, did those other conditions on your 69:22 differential, including pneumothorax, dissection, 69:23 heart attack, were they ruled out?	05_21_18 Jones Combo V7.51
70:1 - 70:4	**Chodos, David 08-05-2017 (00:00:08)** 70:1 THE WITNESS: Yes, sir. Myocardial 70:2 infarction, as well as aortic dissection, as 70:3 well as pneumothorax, were all ruled out by the 70:4 time the patient was discharged.	05_21_18 Jones Combo V7.52
70:25 - 71:2	**Chodos, David 08-05-2017 (00:00:04)** 70:25 Q. but you did refer 71:1 her to an interventional radiologist to have the 71:2 filter removed?	05_21_18 Jones Combo V7.53
71:4 - 71:4	**Chodos, David 08-05-2017 (00:00:01)** 71:4 THE WITNESS: Yes, we did.	05_21_18 Jones Combo V7.54
73:2 - 73:4	**Chodos, David 08-05-2017 (00:00:04)** 73:2 Q. Did you know that she underwent a 73:3 procedure to have the filter removed? 73:4 A. I did.	05_21_18 Jones Combo V7.55
75:3 - 75:5	**Chodos, David 08-05-2017 (00:00:05)** 75:3 Q. This document's entitled "Internal 75:4 Medicine Admit Note." Do you see that? 75:5 A. Yes, sir.	05_21_18 Jones Combo V7.56
76:19 - 77:3	**Chodos, David 08-05-2017 (00:00:33)**	05_21_18 Jones Combo V7.57

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	76:19 A. "Chief complaint, left arm pain and 76:20 dizziness. History of present illness, 50-year-old 76:21 African American female [abbreviated AAF] with 76:22 history significant for hypertension, DVT [which is 76:23 deep vein thrombosis], and peptic ulcer disease. 76:24 Presented to the emergency department yesterday 76:25 complaining of left arm pain evolving into the right 77:1 arm pain as well -- or right arm pain, dizziness, 77:2 diaphoresis while at work. Blood pressure at work 77:3 was elevated.	
77:3 - 77:6	**Chodos, David 08-05-2017 (00:00:13)** 77:3 She 77:4 subsequently experienced another episode of the pain 77:5 and dizziness. On workup in the emergency department 77:6 [or ER], CTA showed a leg of the IVC filter placed	05_21_18 Jones Combo V7.58
77:11 - 77:13	**Chodos, David 08-05-2017 (00:00:08)** 77:11 "Placed status post DVT in 2010 in her 77:12 right pulmonary artery. She denies chest pain, 77:13 nausea/vomiting, dyspnea."	05_21_18 Jones Combo V7.59
80:6 - 80:8	**Chodos, David 08-05-2017 (00:00:07)** 80:6 it appears that you saw her again on 80:7 April 23, 2015, at 6:15. Is that fair? 80:8 A. Yeah, 6:15 in the morning.	05_21_18 Jones Combo V7.60
82:21 - 82:22	**Chodos, David 08-05-2017 (00:00:04)** 82:21 Q. Let's look at your discharge summary. 82:22 A. Yes, sir. Date of discharge was the 24th.	05_21_18 Jones Combo V7.61
86:21 - 87:10	**Chodos, David 08-05-2017 (00:00:51)** 86:21 Q. Explain to 86:22 us what your instructions were to this patient at 86:23 discharge. 86:24 A. All right. So the discharge summary was 86:25 compiled with myself, Dr. Sanchez, and Dr. Jurgensen. 87:1 The advice given to patient will best be seen on 87:2 page 6. 87:3 Q. Go ahead. 87:4 A. "Advice given to patient: Patient was 87:5 advised to continue with followup appointments with 87:6 her primary care provider. Patient was also advised 87:7 to watch her blood pressure in the ambulatory 87:8 setting. Patient was advised to call or directly go	05_21_18 Jones Combo V7.62

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	87:9 to the emergency department if she experienced any 87:10 chest pain or shortness of breath."	
94:9 - 94:12	**Chodos, David 08-05-2017 (00:00:17)** 94:9 Assessment 4, "Normocytic anemia. Iron 94:10 deficient and B12 deficient. Etiology, likely 94:11 secondary to multiple gastric surgeries for ulcers. 94:12 Patient will eventually need screening colonoscopy,	05_21_18 Jones Combo V7.63
94:15 - 95:3	**Chodos, David 08-05-2017 (00:00:47)** 94:15 Sub indent: "Plan, cyanocobalamin, B12, 94:16 1,000-microgram tablet. Take half tablet, 94:17 500 micrograms by mouth daily." 94:18 And the dispensary with that, too, 94:19 60 tablets with 3 refills. 94:20 Next sub indent: "Ferrous sulfate, 94:21 325-milligram tablet. Take one tablet by mouth three 94:22 times daily with meals. Dispense 90 tablets. 94:23 Refills 3." 94:24 And then below that, the next assessment 94:25 will be "IVC component filter embolizing to lung: 95:1 The" -- there's not really much of a plan here, but 95:2 more of a statement: "Remaining component stable, no 95:3 action needed."	05_21_18 Jones Combo V7.107
99:24 - 100:1	**Chodos, David 08-05-2017 (00:00:04)** 99:24 Q. You do not consider yourself to be 99:25 an expert in IVC filters, do you? 100:1 A. No, I do not.	05_21_18 Jones Combo V7.64
100:4 - 100:7	**Chodos, David 08-05-2017 (00:00:06)** 100:4 Q. You ever placed an IVC filter? 100:5 A. I have not. 100:6 Q. Have you ever retrieved an IVC filter? 100:7 A. I have not.	05_21_18 Jones Combo V7.65
102:4 - 102:7	**Chodos, David 08-05-2017 (00:00:15)** 102:4 Q. Let's go back to your care and 102:5 treatment of Ms. Jones, and specifically, I'm going 102:6 to ask you about your first encounter with her on 102:7 April 22, 2015.	05_21_18 Jones Combo V7.66
102:9 - 102:11	**Chodos, David 08-05-2017 (00:00:05)** 102:9 A. Yes, just -- if you want to reference the 102:10 Bates number as well as just what the document is, I 102:11 can probably find it.	05_21_18 Jones Combo V7.67

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102:17 - 103:4	**Chodos, David 08-05-2017 (00:00:30)** 102:17 Q. Ms. Jones presented to 102:18 the emergency department with complaints of 102:19 lightheartedness -- lightheadedness and bilateral arm 102:20 pain, correct? 102:21 A. Yes, ma'am. 102:22 Q. Okay. She actually -- in your note, you 102:23 specifically indicate that she denied chest pain. 102:24 Correct? 102:25 A. Allow me to -- 103:1 Q. It's about -- middle of the paragraph, if 103:2 you look down the left side. The sentence starts, 103:3 "She denies." 103:4 A. Yes, ma'am.	05_21_18 Jones Combo V7.68
103:7 - 104:3	**Chodos, David 08-05-2017 (00:00:39)** 103:7 Q. She denied shortness of breath, correct? 103:8 A. Yes, ma'am. 103:9 Q. She denied back pain -- 103:10 A. Yes, ma'am. 103:11 Q. -- correct? She denied abdominal pain? 103:12 A. Yes, ma'am. 103:13 Q. She denied nausea and vomiting? 103:14 A. Yes, ma'am. 103:15 Q. And she denied any focal weakness; is that 103:16 right? 103:17 A. Yes, ma'am. 103:18 Q. Okay. She told you that she had -- she 103:19 began to have left arm pain, primarily in her 103:20 shoulder, and then it looks like -- it felt like it 103:21 was shooting down her arm to her fingertips; is that 103:22 right? 103:23 A. Yes, ma'am. 103:24 Q. Okay. She also told you that the pain 103:25 waxed and waned; is that correct? 104:1 A. Yes. 104:2 Q. Came and went? 104:3 A. Yes, exactly.	05_21_18 Jones Combo V7.69
105:21 - 107:4	**Chodos, David 08-05-2017 (00:01:02)** 105:21 Q. And under "Respiratory," she denied 105:22 shortness of breath or cough. Correct?	05_21_18 Jones Combo V7.71

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105:23 A. Yes, ma'am.
105:24 Q. Okay. And again, under "Cardiovascular,"
105:25 she denied chest pain. Correct?
106:1 A. Yes, ma'am.
106:2 Q. She denied orthopnea?
106:3 A. Yes, ma'am.
106:4 Q. What is that?
106:5 A. Orthopnea is the -- difficulty with
106:6 breathing --
106:7 Q. Okay.
106:8 A. -- when a patient is laying supine or
106:9 flat.
106:10 Q. Okay. So in other words, she had no
106:11 trouble breathing when she was laying down, correct?
106:12 A. No.
106:13 Q. Okay. And she also denied -- I'm going to
106:14 let you ...
106:15 A. Paroxysmal nocturnal dyspnea.
106:16 Q. Okay. What is that?
106:17 A. Paroxysmal nocturnal dyspnea is a
106:18 phenomenon that occurs when a patient is sleeping,
106:19 they awake short of breath.
106:20 Q. Okay. So she wasn't having any trouble
106:21 waking up with shortness of breath, correct?
106:22 A. No, ma'am.
106:23 Q. Okay. Well, my statement is correct?
106:24 A. Yes, your statement is correct.
106:25 Q. Okay.
107:1 A. She was not having any of those symptoms.
107:2 Q. Okay. She also denied any abdominal pain,
107:3 correct?
107:4 A. Correct.

110:19 - 111:20 **Chodos, David 08-05-2017 (00:01:08)** 05_21_18 Jones Combo V7.74

110:19 Q. Did she have a history of blood clots?
110:20 A. She did have a history of blood clots, of
110:21 DVTs, and that's presumably why the filter was in
110:22 place initially. And we wanted to be very sure that
110:23 there was no remaining blood clot burden in the lower
110:24 extremities if we were to remove the filter.
110:25 Q. Okay. And then under -- your third plan

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	111:1 under the assessment for the filter strut was 111:2 "Patient may benefit from anticoagulation versus 111:3 antiplacement agents, as a portion of the IVC filter 111:4 will be left in the right pulmonary artery." 111:5 Again, that is information that you 111:6 obtained from the interventional radiologist, 111:7 correct? 111:8 A. So, I just want to correct, it was 111:9 "antiplatelet agent." 111:10 Q. Thank you. 111:11 A. And so the first portion of that 111:12 statement, "The patient may benefit," this was 111:13 discussion that the team was having as to the next 111:14 steps following. The second portion, "as a portion 111:15 of the IVC filter will be -- will be left," that was 111:16 after discussion, yes. 111:17 Q. With the interventional radiologist? 111:18 A. Yes. 111:19 Q. To whom you would defer for expertise as 111:20 to that decision, correct?	
111:23 - 111:23	**Chodos, David 08-05-2017 (00:00:00)** 111:23 THE WITNESS: Yes, ma'am.	05_21_18 Jones Combo V7.75
115:8 - 115:13	**Chodos, David 08-05-2017 (00:00:18)** 115:8 Q. In the set of documents that were 115:9 marked as Exhibit -- I think it's 1071. 115:10 A. Okay. 115:11 Q. Would you look at Bates number 65? 115:12 A. Yeah. 115:13 Q. And is that a progress note	05_21_18 Jones Combo V7.80
115:16 - 116:4	**Chodos, David 08-05-2017 (00:00:31)** 115:16 A. I cannot recall ever reviewing the medical 115:17 record in its entirety, but this appears to be a 115:18 document from the record. 115:19 Q. Okay. And do you see where it says, 115:20 "Nelson," in the bottom right, under the illegible 115:21 signature? 115:22 A. Yes, ma'am. 115:23 Q. And do you understand that Dr. Nelson was 115:24 the interventional radiologist who treated Ms. Jones 115:25 for the IVC filter and the fractured strut?	05_21_18 Jones Combo V7.81

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	116:1 A. Yes, ma'am. 116:2 Q. Okay. And on the one, two, three, fourth 116:3 line down from the top, do you see the sentence that 116:4 starts "No"?	
116:10 - 116:13	**Chodos, David 08-05-2017 (00:00:09)** 116:10 A. Yes. 116:11 Q. Okay. And that sentence reads: No 116:12 intervention needed for embolized leg as it is in a 116:13 safe location.	05_21_18 Jones Combo V7.82
116:16 - 116:21	**Chodos, David 08-05-2017 (00:00:10)** 116:16 Q. Did I read that correctly? 116:17 A. Yes, that is as it appears. 116:18 Q. Okay. And you would, again, defer to 116:19 Dr. Nelson, the interventional radiologist, to make 116:20 that determination. Correct? 116:21 A. Yes, ma'am.	05_21_18 Jones Combo V7.83
117:2 - 117:22	**Chodos, David 08-05-2017 (00:01:01)** 117:2 Q. You noted that Ms. Jones suffered from an 117:3 iron deficiency. Is that right? 117:4 A. Yes, ma'am. 117:5 Q. And eventually you prescribed her with 117:6 medication for that iron deficiency, correct? 117:7 A. Indeed, we did prescribe medication for 117:8 iron deficiency. 117:9 Q. Okay. What are some of the symptoms of 117:10 iron deficiency? 117:11 A. Iron deficiency can, again, be a disease 117:12 that has no symptomatic manifestation. Some of the 117:13 very typical symptoms we will look for would include 117:14 numbness or tingling. Paresthesias, as they're 117:15 called. 117:16 Q. Okay. 117:17 A. Can also include symptoms such as restless 117:18 leg syndrome, and can also include cravings for ice. 117:19 Q. What about weakness or fatigue? 117:20 A. These can also be manifested with iron 117:21 deficiency. 117:22 Q. And what about lightheadedness?	05_21_18 Jones Combo V7.84
117:24 - 118:2	**Chodos, David 08-05-2017 (00:00:07)** 117:24 THE WITNESS: Less so with iron	05_21_18 Jones Combo V7.85

Page/Line	Source	ID
	117:25 deficiency. However, you can see that with 118:1 blood loss, which can sometimes be associated 118:2 with iron deficiency.	
124:16 - 124:23	**Chodos, David 08-05-2017 (00:00:25)** 124:16 Q. Then, for the admitting diagnosis 124:17 of bilateral arm -- I can't say that word -- 124:18 A. Paresthesias. 124:19 Q. -- paresthesias, you indicate "secondary 124:20 to iron deficiency." Did I read that correctly? 124:21 A. Yes, ma'am. 124:22 Q. So you attribute her complaints of 124:23 bilateral arm pain to her iron deficiency, correct?	05_21_18 Jones Combo V7.86
124:25 - 124:25	**Chodos, David 08-05-2017 (00:00:00)** 124:25 THE WITNESS: Yes, ma'am.	05_21_18 Jones Combo V7.87
125:13 - 127:22	**Chodos, David 08-05-2017 (00:02:40)** 125:13 Q. Also, while she was in the 125:14 hospital, you determined that she had -- will you say 125:15 that first word for me? 125:16 A. Normocytic. 125:17 Q. Normocytic anemia. What is that? 125:18 A. Normocytic anemia -- "normocytic" refers 125:19 to the actual size of the red blood cell on a 125:20 conventional CBC, which is a complete blood count. 125:21 You get data such as your white blood cell count, 125:22 your hemoglobin, your hematocrit, but you also get a 125:23 value called your mean MCV. 125:24 And this MCV is reported as basically a 125:25 volume size, and you can have a normal range, which 126:1 is roughly 80 to 100. You can have macrocytosis, 126:2 which is higher than that, and you can have 126:3 microcytosis, which is roughly lower than that. 126:4 "Normocytic" refers to the fact that there 126:5 was an anemia present, so her hemoglobin and 126:6 hematocrit were low; however, the MCV was within the 126:7 normal range. 126:8 Q. Okay. In lay terms, you diagnosed her as 126:9 suffering from anemia; is that correct? 126:10 A. Yes, ma'am. 126:11 Q. Okay. And what are some of the symptoms 126:12 of anemia?	05_21_18 Jones Combo V7.108

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126:13 A. Anemia can present with fatigue, profound
126:14 weakness. Other symptoms will also -- I mentioned
126:15 earlier, you can see sometimes, depending on the
126:16 etiology of the anemia. So some can include cravings
126:17 for ice; that's what you'll see with the -- the
126:18 typically iron-deficient anemias. And you'll
126:19 sometimes see those paresthesias with the iron
126:20 deficiency anemias.
126:21 The B12 deficiency anemias sometimes
126:22 present with balance-related issues, and those are
126:23 usually macrocytic. Normocytic can be a combination
126:24 of the two.
126:25 So, again, the etiology of the anemia is
127:1 crucially important, and is usually part of our
127:2 workup in the hospital and can determine what the
127:3 symptoms usually are that cause for presentation.
127:4 Q. Okay. You also noted in your discharge
127:5 her history of upper gastrointestinal bleed; is that
127:6 correct?
127:7 A. Yes, ma'am.
127:8 Q. Okay. That's something you learned about
127:9 while she was in the hospital, correct?
127:10 A. I believe we learned that from her when
127:11 she was in the emergency department, when we were
127:12 admitting her to the hospital.
127:13 Q. Okay. You also noted, again, her history
127:14 of pancreatitis as being asymptomatic at the time,
127:15 and her history of deep vein thrombosis, and then
127:16 you've added to that and found that she did not have
127:17 any at that time, correct?
127:18 A. Yes, the ultrasound was negative for lower
127:19 extremity deep vein thrombosis.
127:20 Q. Okay. And then if we go to the next page
127:21 of your discharge summary, you talked about it
127:22 before, her hospital course.

130:6 - 130:9 **Chodos, David 08-05-2017 (00:00:09)** 05_21_18 Jones Combo V7.90

130:6 Q. But if Dr. Nelson stated in her
130:7 record that the strut was not in an area that was
130:8 going to cause any problems, you would defer to her
130:9 for that; is that correct?

Page/Line	Source	ID
130:11 - 130:11	**Chodos, David 08-05-2017 (00:00:01)** 130:11 THE WITNESS: I would defer to Dr. Nelson.	05_21_18 Jones Combo V7.91
133:15 - 133:17	**Chodos, David 08-05-2017 (00:00:09)** 133:15 Q. After you discharged Ms. Jones, she 133:16 came back to see you on May 11, 2015, correct? 133:17 A. Yes, ma'am.	05_21_18 Jones Combo V7.93
135:23 - 136:4	**Chodos, David 08-05-2017 (00:00:23)** 135:23 Q. And then you record, "Patient has 135:24 not been taking any of her medications." 135:25 Did I read that correctly? 136:1 A. Yes. 136:2 Q. If she was not taking her medications, 136:3 then her anemia, her iron deficiency, and her B12 136:4 deficiency were not being treated; is that correct?	05_21_18 Jones Combo V7.94
136:6 - 136:25	**Chodos, David 08-05-2017 (00:00:44)** 136:6 THE WITNESS: At -- at that time, no. 136:7 However, she did receive treatment in the 136:8 hospital. 136:9 BY MS. HELM: 136:10 Q. Okay. But between her discharge from the 136:11 hospital on April 24, 2015, until you saw her on 136:12 May 11, 2015, she indicated to you that she had not 136:13 been taking the medications you prescribed to her 136:14 upon discharge; is that right? 136:15 A. That is correct. 136:16 Q. Okay. And you prescribed those 136:17 medications for a reason, didn't you? 136:18 A. Those medications were prescribed for what 136:19 was -- what was elucidated on hospital -- her 136:20 hospital stay, specifically to treat the various 136:21 conditions that were found, and as primary 136:22 prophylaxis -- 136:23 Q. Okay. 136:24 A. -- for vascular disease. 136:25 Q. Including her anemia, her iron deficiency,	05_21_18 Jones Combo V7.95
137:1 - 137:2	**Chodos, David 08-05-2017 (00:00:01)** 137:1 correct? 137:2 A. Yes, ma'am.	05_21_18 Jones Combo V7.109
137:19 - 138:10	**Chodos, David 08-05-2017 (00:00:40)** 137:19 Q. Okay. And then you again said, "Patient	05_21_18 Jones Combo V7.96

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137:20 was stressed medication adherence and to check her
137:21 blood pressure ambulatory." Correct?
137:22 A. Yes.
137:23 Q. Okay. You're telling Ms. Jones she needs
137:24 to take her medication, correct?
137:25 A. We reinforced the importance of taking
138:1 medicine as well as checking blood pressure.
138:2 Q. Okay.
138:3 A. And again, I'd like -- I'd like to note
138:4 right now that this note was reviewed by Dr. Laura
138:5 Denton, so there may be amendments that she has made
138:6 to the clinic note.
138:7 Q. Okay. Either you or Dr. Denton stressed
138:8 to Ms. Jones that she needed to be taking her
138:9 medication, correct?
138:10 A. Yes.

141:23 - 142:16 **Chodos, David 08-05-2017 (00:00:52)** 05_21_18 Jones Combo V7.98

141:23 Q. And then below that it says, "IVC
141:24 filter component embolizing to lung. Remaining
141:25 component stable. No action needed."
142:1 Did I read that correct?
142:2 A. You did.
142:3 Q. And that "remaining component" refers to
142:4 the strut in the pulmonary artery, correct?
142:5 A. That it does.
142:6 Q. Okay. And as you've discussed earlier,
142:7 the team of physicians at Memorial Hospital -- and
142:8 you defer to the interventional radiologist --
142:9 decided that no future action was needed regarding
142:10 that remaining strut, correct?
142:11 A. To the best of my knowledge, yes, as well
142:12 as their expertise I have to defer to.
142:13 Q. Okay. And you defer to the other experts
142:14 who decided not to place Ms. Jones on
142:15 anticoagulation, correct?
142:16 A. Yes.

152:3 - 152:19 **Chodos, David 08-05-2017 (00:00:58)** 05_21_18 Jones Combo V7.102

152:3 Q. did Dr. Nelson describe
152:4 why she decided to remove the filter?
152:5 A. In her note, I do not believe there's --

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	152:6 Q. See where she begins, it says, "No 152:7 intervention for embolized leg, as it is in a safe 152:8 location, but will remove filter." 152:9 Do you see the rest of that? 152:10 A. Yeah. 152:11 Q. Can you read that into the record? 152:12 A. I certainly can. So, following that: 152:13 "... but will remove filter due to 152:14 embolization risks if additional struts should break 152:15 as [something] is showing signs of structural fatigue 152:16 and stress." 152:17 Q. And finish -- 152:18 A. "As filter" -- I'm sorry, yes, "as filter 152:19 is showing signs of structural fatigue and stress."	
160:4 - 160:7	**Chodos, David 08-05-2017 (00:00:07)** 160:4 Q. And you wrote in your record why it 160:5 remained behind. Is that fair? 160:6 A. Yes. 160:7 Q. Read what you said.	05_21_18 Jones Combo V7.103
160:16 - 160:21	**Chodos, David 08-05-2017 (00:00:18)** 160:16 "Patient also went to the angio suite to 160:17 have her IVC filter removed with interventional 160:18 radiology. The portion that was lodged in the right 160:19 pulmonary artery, however remained behind as that it 160:20 was in a dangerous area and was not suitable for 160:21 removal."	05_21_18 Jones Combo V7.106
176:13 - 176:18	**Chodos, David 08-05-2017 (00:00:25)** 176:13 Q. And certainly you cannot say, will not say 176:14 that any of her other conditions -- hypertension, 176:15 B12 deficiency, iron deficiency, anemia, peptic ulcer 176:16 disease -- you cannot and will not say that those 176:17 have any relation to the need to have her filter 176:18 removed. Is that fair?	05_21_18 Jones Combo V7.104
176:20 - 176:21	**Chodos, David 08-05-2017 (00:00:06)** 176:20 THE WITNESS: The comorbidities have no 176:21 bearing on her filter needing to be removed.	05_21_18 Jones Combo V7.105

Plaintiffs Designations = 00:08:18

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Defense Designations = 00:21:50

Plaintiffs and Defense Designations = 00:02:19

Total Time = 00:32:27

Exhibit D

Designation Run Report

Civarella 11-12-14 Jones Trial Depo Designations V3

Ciavarella, David 11-12-2013

Plaintiffs Designations 00:20:25

Defense Designations 00:08:18

P & D Affimatives 00:09:33

Total Time 00:38:16

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11:9 - 11:11	**Ciavarella, David 11-12-2013 (00:00:04)** 11:9 Q. Good morning. Would you please state 11:10 your full name? 11:11 A. Yeah, David Ciavarella.	05_14_18 Combo Jone V3.1
36:9 - 36:19	**Ciavarella, David 11-12-2013 (00:00:27)** 36:9 Q. Have you ever considered doing a 36:10 retrospective analysis or study to submit to a 36:11 peer-reviewed article as they relate to any of 36:12 the Bard IVC filters? 36:13 A. No. 36:14 Q. Have you ever considered looking at 36:15 any of the adverse events and the details of the 36:16 adverse events and submitting it -- one or more 36:17 of those to publication as a case report or a 36:18 case series? 36:19 A. No.	05_14_18 Combo Jone V3.4
36:20 - 37:3	**Ciavarella, David 11-12-2013 (00:00:26)** 36:20 Q. Why wouldn't you want to do something 36:21 like that? 36:22 A. Well, two main reasons. One is it's 36:23 not my expertise. The people who utilize, treat 36:24 patients every day are the experts. My role is 36:25 no longer direct patient care. 37:1 Q. Right. 37:2 A. And, you know, secondly, it's a matter 37:3 of priority. I have other things to do.	05_14_18 Combo Jone V3.5
43:15 - 43:20	**Ciavarella, David 11-12-2013 (00:00:16)** 43:15 Q. And when was the last time before 2003 43:16 that you had actually had an interaction with a 43:17 patient where you were getting their informed 43:18 consent or recommending various types of 43:19 alternative therapeutic, you know, remedies? 43:20 A. 1995.	05_14_18 Combo Jone V3.6
45:7 - 45:13	**Ciavarella, David 11-12-2013 (00:00:17)** 45:7 Q. Well, what's a health hazard 45:8 evaluation? 45:9 A. Well, it's a document -- it's a 45:10 document written to provide a health care 45:11 professional evaluation of a complaint or a 45:12 hazard reported to a company concerning one of	05_14_18 Combo Jone V3.7

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	45:13 its products.	
48:25 - 49:8	**Ciavarella, David 11-12-2013 (00:00:39)**	05_14_18 Combo Jone V3.8
	48:25 Q. Now, these health hazard evaluations 49:1 that you agreed with the definition that I gave 49:2 you, they involve also whoever was doing these, 49:3 that person making decisions about whether or 49:4 not, you know, there was a likelihood of a 49:5 recurrence of the problem; right? They made 49:6 those calls? 49:7 A. They didn't make those calls. We 49:8 provided our assessment.	
61:13 - 61:17	**Ciavarella, David 11-12-2013 (00:00:13)**	05_14_18 Combo Jone V3.9
	61:13 Q. And that's why we -- some doctors 61:14 think that these filters should be put in place 61:15 to prevent that sort of event from happening in 61:16 patients who are at risk of that happening? 61:17 A. Yes.	
61:18 - 61:24	**Ciavarella, David 11-12-2013 (00:00:19)**	05_14_18 Combo Jone V3.10
	61:18 Q. And that -- when we talk about the 61:19 benefit of an IVC filter and risk analysis, 61:20 we're talking about the benefit of that filter 61:21 staying where it was put and stopping a clot 61:22 from reaching either the heart or the lungs; 61:23 right? 61:24 A. Yes.	
75:14 - 75:17	**Ciavarella, David 11-12-2013 (00:00:21)**	05_14_18 Combo Jone V3.11 CIAVARELLA21.1.2 CIAVARELLA21.1.4
	75:14 MR. LOPEZ: No. 21 is regulatory 75:15 affairs manual, Bard, with Bates Nos. 75:16 BPV-17-01-00024667, through and including 75:17 684.	
76:6 - 76:13	**Ciavarella, David 11-12-2013 (00:00:26)**	05_14_18 Combo Jone V3.12 clear
	76:6 Q. And this was the manual that -- 76:7 at least internally at Bard that they imposed 76:8 upon themselves to dictate whether a product 76:9 should be recalled or whatever type of safety 76:10 action should be taken with respect to their 76:11 products; correct? 76:12 A. Yeah, well, it's a document describing 76:13 how they should go about remedial action plans.	
77:2 - 77:9	**Ciavarella, David 11-12-2013 (00:00:38)**	05_14_18 Combo Jone V3.13

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	77:2 Q. And would you agree with me that if a 77:3 product had an unacceptable risk, that it's a 77:4 product that probably should be recalled? 77:5 A. If a product has an unacceptable risk 77:6 that can't be mitigated in any way or if the 77:7 benefit to patients is outweighed by the risk, 77:8 then I imagine that a company would decide to no 77:9 longer sell that product.	
80:4 - 80:13	**Ciavarella, David 11-12-2013 (00:00:32)** 80:4 Q. And, by the way, the company shouldn't 80:5 make these decisions based in any way on a 80:6 potential adverse effect on market share or 80:7 profitability or income; right? That would be 80:8 wrong? 80:9 A. The decision to recall a product 80:10 should be based upon the safety profile, the 80:11 risk/benefit analysis of that product and its 80:12 effect on patients and on, you know, the users 80:13 of the product.	05_14_18 Combo Jone V3.14
84:22 - 85:3	**Ciavarella, David 11-12-2013 (00:00:15)** 84:22 Q. The company shouldn't 84:23 determine whether or not this type of severity 84:24 and this type of adverse reaction and this 84:25 frequency is at a level that all doctors should 85:1 accept, doctors have -- all doctors and patients 85:2 have a right to make that decision on their 85:3 own --	05_14_18 Combo Jone V3.15
86:7 - 86:16	**Ciavarella, David 11-12-2013 (00:00:42)** 86:7 THE WITNESS: Yeah, I don't know 86:8 how to answer that question. Whenever a 86:9 company makes a product, develops a product 86:10 for use, it makes an assessment of the 86:11 frequency with which it might fail or be 86:12 associated with an adverse outcome. And 86:13 when those numbers are low enough, I don't 86:14 know what would be gained by trying to 86:15 describe in every circumstance that much 86:16 detail.	05_14_18 Combo Jone V3.16
94:3 - 94:7	**Ciavarella, David 11-12-2013 (00:00:14)** 94:3 Q. Okay. I understand. And if the	05_14_18 Combo Jone V3.17

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	94:4 doctor has a certain expectation about a device, 94:5 it's important for him to have that information 94:6 as to whether or not this device is going to 94:7 meet his expectations; right?	
94:9 - 94:9	**Ciavarella, David 11-12-2013 (00:00:00)** 94:9 THE WITNESS: Yes.	05_14_18 Combo Jone V3.18
104:16 - 104:18	**Ciavarella, David 11-12-2013 (00:00:10)** 104:16 Q. What is MAUDE? 104:17 A. That's the FDA's database for medical 104:18 device reporting.	05_14_18 Combo Jone V3.19
106:9 - 106:23	**Ciavarella, David 11-12-2013 (00:00:42)** 106:9 Q. I'm just trying to find out 106:10 from you what your position and Bard's position 106:11 is about the significance of what is being 106:12 reported and trended via the MAUDE database. 106:13 A. Well -- 106:14 Q. Can you tell me what that is? 106:15 A. -- with respect to our own reports 106:16 that we provide to the MAUDE database, we 106:17 already know that information. So whether that 106:18 information goes to the MAUDE database or not, 106:19 Bard has access to that information and can use 106:20 it to assure the quality of its product. 106:21 With respect to our competitors' 106:22 information, it's a very imperfect and, 106:23 therefore, unreliable database.	05_14_18 Combo Jone V3.20
110:21 - 111:3	**Ciavarella, David 11-12-2013 (00:00:23)** 110:21 Q. Again, looking at Exhibit 110:22 21, this is the -- at least the internal 110:23 document that should have guided Bard in its 110:24 assessment and evaluation and determination as 110:25 to whether or not the Recovery or any version of 111:1 the G2 should have been recalled from the 111:2 market; is that right? 111:3 A. Yes.	05_14_18 Combo Jone V3.21
131:6 - 131:12	**Ciavarella, David 11-12-2013 (00:00:15)** 131:6 Q. But there's a general consensus 131:7 that that might be, in fact, the case, you're 131:8 only getting 1 to 5 percent of what's actually 131:9 happening, actually reported to the company or	05_14_18 Combo Jone V3.22

Page/Line	Source	ID
	131:10 FDA? 131:11 A. I mean, maybe yes, maybe no. That's 131:12 the problem with it is you don't know.	
131:16 - 131:23	**Ciavarella, David 11-12-2013 (00:00:19)** 131:16 Q. But there was at one point in 131:17 time -- I can show you the document later -- 131:18 where you, Dr. Ciavarella, said one of the 131:19 problems with reporting of events, voluntary 131:20 reporting, is there's a consensus that you might 131:21 be only getting 1 to 5 percent of the actual 131:22 events; right? 131:23 A. Could be. Yeah, there's a consensus.	05_14_18 Combo Jone V3.23
174:22 - 175:9	**Ciavarella, David 11-12-2013 (00:00:50)** 174:22 Q. let's look at the caval 174:23 perforation issue that we talked about earlier 174:24 as it relates to the G2. If you look at the 174:25 rates -- by the way, that does say "Rates," 175:1 doesn't it, in the column? They use the word 175:2 "Rates"? 175:3 A. Down at the bottom they do, yeah. 175:4 Q. Okay. And according to this data, the 175:5 rates of caval perforations compared to the SNF 175:6 and the G2, is the G2 is still, at least 175:7 according to this data, about -- what's that, 175:8 about 800 percent greater? 175:9 A. No.	05_14_18 Combo Jone V3.24
175:10 - 175:12	**Ciavarella, David 11-12-2013 (00:00:02)** 175:10 Q. I'm just asking you to do some math 175:11 with me. 175:12 A. You're misinterpreting the data.	05_14_18 Combo Jone V3.25
176:2 - 176:8	**Ciavarella, David 11-12-2013 (00:00:14)** 176:2 Q. If you 176:3 look at the difference between the rates that 176:4 are reported on this document, the rates of 176:5 caval perforations are greater for the G2 when 176:6 compared to both the Recovery and the Simon 176:7 Nitinol filter? 176:8 A. Yes.	05_14_18 Combo Jone V3.26
179:16 - 179:25	**Ciavarella, David 11-12-2013 (00:00:32)** 179:16 Q. Well, eventually didn't Dr. Lehmann	05_14_18 Combo Jone V3.27

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	179:17 take some of this data -- I don't know what time 179:18 period it was -- the MAUDE data, and determine 179:19 that there was a statistically significant 179:20 increased risk of migration, perforation, 179:21 fractures, and other complications involved with 179:22 the Recovery filter when compared to all other 179:23 filters on the market by a factor of somewhere 179:24 between the low 4s and the mid 5s? 179:25 A. Yeah.	
180:2 - 180:9	**Ciavarella, David 11-12-2013 (00:00:28)** 180:2 A. He did an analysis based on reported 180:3 rates from MAUDE and made some statistical 180:4 comparisons which he said were really not valid. 180:5 Q. Well, he said they were statistically 180:6 significant. 180:7 A. Well, the statistical test was done, 180:8 but the use of those data are not appropriate 180:9 for comparison rates.	05_14_18 Combo Jone V3.28
180:15 - 180:21	**Ciavarella, David 11-12-2013 (00:00:20)** 180:15 Q. -- he said that these increased risks 180:16 of somewhere between 400 percent and 500 percent 180:17 were statistically significant when compared to 180:18 all other filters on the market; right? 180:19 A. I don't remember the exact numbers, 180:20 but, yes, he did make some statements about 180:21 statistically significant differences.	05_14_18 Combo Jone V3.29
182:24 - 182:25	**Ciavarella, David 11-12-2013 (00:00:06)** 182:24 Exhibit 28 is 182:25 a PowerPoint.	05_14_18 Combo Jone V3.30 CIAVARELLA28.1.1
183:4 - 183:5	**Ciavarella, David 11-12-2013 (00:00:07)** 183:4 And it's a filters 183:5 complaint history data as of 7/31/07.	05_14_18 Combo Jone V3.31 CIAVARELLA28.1.5
184:21 - 184:24	**Ciavarella, David 11-12-2013 (00:00:11)** 184:21 aren't we talking about frequency 184:22 when you look at rates? 184:23 A. Yes, frequency. Rate is just a way 184:24 to -- one way to describe a frequency.	05_14_18 Combo Jone V3.32 clear
184:25 - 185:11	**Ciavarella, David 11-12-2013 (00:00:33)** 184:25 Q. Did you have any better data, by the 185:1 way, that would give us rates or frequency in	05_14_18 Combo Jone V3.33

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	185:2 comparing Recovery or G2 to competitive products 185:3 or the Recovery in G2 to the Simon Nitinol 185:4 filter? 185:5 A. Well, I think the only other way to 185:6 make comparisons, and it's very difficult to do 185:7 so, would be by analysis of published literature 185:8 in journal articles, so if you had an article 185:9 published about an adverse event profile of one 185:10 of our competitors versus papers that had been 185:11 published on our filter.	
205:25 - 206:8	**Ciavarella, David 11-12-2013 (00:00:27)** 205:25 Q. We've been talking about, you know, 206:1 migration and embolization of the entire filter, 206:2 but you've learned that you can have 206:3 embolization of just a fragment of an IVC filter 206:4 that can migrate to the heart and cause a 206:5 fatality; true? 206:6 A. Yes, true. I just don't remember if 206:7 it caused a fatality. I know it caused some 206:8 serious adverse events.	05_14_18 Combo Jone V3.34
206:16 - 207:11	**Ciavarella, David 11-12-2013 (00:01:10)** 206:16 What are some of the 206:17 risks associated with such an event? 206:18 A. Well, if a -- if the piece of metal 206:19 moves up into the heart, the danger is that it 206:20 could potentially pierce some critical structure 206:21 in the heart, either a heart valve or the heart 206:22 muscle itself, cause an arrhythmia, cause 206:23 bleeding around the heart. 206:24 Q. I think you wrote in one of your HHEs 206:25 that it could even cause a stroke, you can have 207:1 a stroke from a fragment? 207:2 A. If the fragment moved from the right 207:3 atrium to the left atrium and then entered the 207:4 circulation on the left side, you could have a 207:5 stroke, yes. 207:6 Q. So that's a risk -- that's a 207:7 catastrophic risk associated with a fracture 207:8 fragment from an IVC filter? 207:9 A. That's a -- those are theoretical	05_14_18 Combo Jone V3.35

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	207:10 risks and I believe, as I remember fairly well, 207:11 that some of those happened.	
247:15 - 247:20	**Ciavarella, David 11-12-2013 (00:00:20)** 247:15 Q. Well, let me ask you, how many of the 247:16 five people between December 2004 and June of 247:17 2005 who had these migrations were aware of the 247:18 ten that happened before? 247:19 A. I don't know. 247:20 Q. Probably none of them; right?	05_14_18 Combo Jone V3.36
247:22 - 247:23	**Ciavarella, David 11-12-2013 (00:00:01)** 247:22 THE WITNESS: Potentially none of 247:23 them.	05_14_18 Combo Jone V3.37
250:2 - 250:5	**Ciavarella, David 11-12-2013 (00:00:10)** 250:2 Q. Would it be reasonable for a doctor 250:3 who's considering using a Recovery filter in 250:4 2005 to want to know whether or not that device 250:5 had a higher failure rate than other devices?	05_14_18 Combo Jone V3.38
250:7 - 250:7	**Ciavarella, David 11-12-2013 (00:00:00)** 250:7 THE WITNESS: Yes.	05_14_18 Combo Jone V3.39
250:9 - 250:12	**Ciavarella, David 11-12-2013 (00:00:09)** 250:9 Q. Would you also agree that he couldn't 250:10 do a proper analysis without knowing all of the 250:11 risks, not only the type of risk but the 250:12 frequency of risk?	05_14_18 Combo Jone V3.40
250:14 - 250:15	**Ciavarella, David 11-12-2013 (00:00:03)** 250:14 THE WITNESS: Well, if he -- 250:15 sure, if he didn't have the information.	05_14_18 Combo Jone V3.41
265:18 - 265:21	**Ciavarella, David 11-12-2013 (00:00:30)** 265:18 Q. No. 33 is a December 27, 2005, 265:19 document, which is an e-mail string that starts 265:20 with a December 20, 2005, e-mail from a Cindi 265:21 Walcott to you, Dr. Ciavarella.	05_14_18 Combo Jone V3.42 BPVE.1 - BPVE.1.1 BPVE.2 - BPVE.2.1
267:16 - 267:23	**Ciavarella, David 11-12-2013 (00:00:17)** 267:16 Q. you can read the 267:17 whole thing if you need to and I'll, of course, 267:18 allow you, but this involved a conference call 267:19 with the design team of the G2 filter and Chris 267:20 Ganser, caudal migrations of the G2 were briefly 267:21 discussed, that's what it says there in the 267:22 e-mail; right?	05_14_18 Combo Jone V3.43 BPVE.2.2

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	267:23 A. Yes.	
267:24 - 267:24	**Ciavarella, David 11-12-2013 (00:00:01)**	05_14_18 Combo Jone V3.44
	267:24 Q. And what's a caudal migration?	clear
268:4 - 268:5	**Ciavarella, David 11-12-2013 (00:00:04)**	05_14_18 Combo Jone V3.45
	268:4 A. It means downward basically, so toward 268:5 the feet.	
268:6 - 268:15	**Ciavarella, David 11-12-2013 (00:00:40)**	05_14_18 Combo Jone V3.46
	268:6 Q. And from a patient safety and even 268:7 from an efficacy standpoint, why would a company 268:8 want to be concerned about caudal migrations? 268:9 A. Well, first, the filter is designed 268:10 with the intent of staying in place, and so 268:11 migrations in either direction would be 268:12 something that they would try to understand the 268:13 cause for that and -- you know, and also 268:14 understand if there were any possible adverse 268:15 outcomes based on a caudal migration.	
272:5 - 272:15	**Ciavarella, David 11-12-2013 (00:00:18)**	05_14_18 Combo Jone V3.47
	272:5 Q. Well, we know that the G2 is a 272:6 different design than the Recovery; right? 272:7 A. We do. 272:8 Q. And we do know that it was a different 272:9 design than the Simon Nitinol filter? 272:10 A. Yes. 272:11 Q. There was something about the design 272:12 of the G2 that for some reason you were getting 272:13 reports of a downward migration of more than 272:14 2 centimeters; correct? 272:15 A. Yes.	
272:24 - 273:21	**Ciavarella, David 11-12-2013 (00:00:55)**	05_14_18 Combo Jone V3.48
	272:24 And this was something 272:25 that the company was recognizing early in the 273:1 marketing of the G2? 273:2 A. Yes. 273:3 Q. And, by the way, the G2 went through a 273:4 510(k), you know, process as well? 273:5 A. Yes. 273:6 Q. And it was represented to be, 273:7 therefore, substantially equivalent from safety 273:8 and efficacy to all of its predicate devices?	

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	273:9 A. Yes. Again, you know, the regulatory	
	273:10 terminology, right.	
	273:11 equivalent to whatever predicates were used, I	
	273:12 presume the Recovery, but I don't -- I think it	
	273:13 was much closer in design to the Recovery than	
	273:14 it was to the Simon Nitinol.	
	273:15 Q. And would you agree with others that	
	273:16 have testified before you that it was designed	
	273:17 to resolve some of the issues that existed with	
	273:18 the Recovery filter --	
	273:19 A. Yes.	
	273:20 Q. -- migration, fracture?	
	273:21 A. Those are the two biggest.	
273:22 - 274:6	**Ciavarella, David 11-12-2013 (00:00:27)**	05_14_18 Combo Jone V3.49
	273:22 Q. And then you write back to Cindi and	
	273:23 again carbon copy Shari Allen and Gin Schulz on	
	273:24 Page 1, the first -- the top page of this	
	273:25 Exhibit -- what's the number again, thirty --	
	274:1 A. 3.	
	274:2 Q. -- 33 -- I'm going to write 33 on my	
	274:3 copy -- "Thank you Cindi. I think we should	BPVE.1.2
	274:4 discuss these further so I can get a better	
	274:5 understanding of each one. But first, it would	
	274:6 help if I had a little more information."	
274:7 - 275:6	**Ciavarella, David 11-12-2013 (00:01:00)**	05_14_18 Combo Jone V3.50
	274:7 Did I read that correctly?	clear
	274:8 A. Uh-huh, yes.	
	274:9 Q. And then you wrote: "From what you've	BPVE.1.3
	274:10 sent me, it seems to me that the biggest (worst	
	274:11 case) consequence of these migrations is that	
	274:12 they are accompanied in a majority of cases by	
	274:13 tilting."	
	274:14 Do you see that?	
	274:15 A. Yes.	
	274:16 Q. And by "these migrations," you mean a	clear
	274:17 downward -- i.e., caudal -- migration?	
	274:18 A. Yes.	
	274:19 Q. And we talked about tilting earlier.	
	274:20 Remember that?	
	274:21 A. Yes.	

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	274:22 Q. And what did you mean by the worst 274:23 case/biggest consequence would be tilting? 274:24 A. Well, what my concern with in that 274:25 paragraph was that the filter, which is 275:1 conically shaped when it's placed upright, as it 275:2 fell would also turn over on its side like a 275:3 Christmas tree when it was placed and then 275:4 fallen over lying in the vein in a -- in a 275:5 horizontal orientation instead of a vertical 275:6 orientation.	
275:19 - 276:9	**Ciavarella, David 11-12-2013 (00:00:44)** 275:19 Q. And then you wrote: "This raises the 275:20 concern of lack of efficacy..."; right? And by 275:21 "lack of efficacy," meaning in that position the 275:22 device may not be able to stop the type of clots 275:23 that it's designed to stop and for the reason 275:24 for which it was placed? 275:25 A. That's my concern, yeah. That was it. 276:1 Q. In fact, you say "...to perform clot 276:2 interruption," you actually say it in this 276:3 e-mail; right? 276:4 A. Yes. 276:5 Q. While I'm thinking about it, when the 276:6 G2 was approved for marketing, it was approved 276:7 as a permanent device, not a retrievable device; 276:8 correct? 276:9 A. Correct.	05_14_18 Combo Jone V3.51 BPVE.1.4 clear
276:17 - 276:20	**Ciavarella, David 11-12-2013 (00:00:10)** 276:17 Q. So when the Recovery was removed from 276:18 the market, the company no longer had a 276:19 retrievable device that it could sell? 276:20 A. Correct.	05_14_18 Combo Jone V3.52
276:21 - 276:23	**Ciavarella, David 11-12-2013 (00:00:06)** 276:21 Q. Until the G2 got its retrievable 276:22 indication about two years later; right? 276:23 A. Correct.	05_14_18 Combo Jone V3.53
277:11 - 278:10	**Ciavarella, David 11-12-2013 (00:01:00)** 277:11 Q. Okay. The next sentence is: "I would 277:12 like to look more generally at the G2 277:13 complaints. I have seen problems with caudal	05_14_18 Combo Jone V3.54 BPVE.1.6

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	277:14 migration, tilting, perforation, mis-deployment 277:15 and maybe one or two additional things." 277:16 You wrote that? 277:17 A. Yes. 277:18 Q. And so in the early weeks or few 277:19 months that the product was on the market, you 277:20 were already seeing yourself personally issues 277:21 involving caudal migration, tilting, and 277:22 perforation; right? 277:23 A. Yes. 277:24 Q. And then you ask: "Can you tell me 277:25 the total number of complaints (not damaged 278:1 packages and the like) and total number of units 278:2 distributed?" 278:3 You asked that important question? 278:4 A. Yes. 278:5 Q. And that important question dealt with 278:6 a lot of the data we've been talking about 278:7 today, that is, how many units do we have that 278:8 are sold and how many complaints do we have from 278:9 doctors that have been using the product? 278:10 A. Right.	BPVE.1.7 clear
278:13 - 278:16	**Ciavarella, David 11-12-2013 (00:00:09)** 278:13 Q. Why would you want that information? 278:14 A. Well, it's -- it's part of the 278:15 information that we have been collecting and 278:16 looking at all this time.	05_14_18 Combo Jone V3.55
279:5 - 279:12	**Ciavarella, David 11-12-2013 (00:00:22)** 279:5 Q. I'm saying as 279:6 far as data that you requested of Cindi, you 279:7 asked her specifically for the number of MDRs 279:8 that you had for G2, the total number of 279:9 complaints, and the total number of units 279:10 distributed. That was important for you to have 279:11 to evaluate this problem? 279:12 A. Right	05_14_18 Combo Jone V3.56
279:12 - 279:16	**Ciavarella, David 11-12-2013 (00:00:11)** 279:12 A. But it was just a starting 279:13 point. So then I would go on to our TrackWise 279:14 system in which details of the complaints were	05_14_18 Combo Jone V3.57

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	279:15 entered and review all of them, which is what I 279:16 would do.	
280:8 - 280:20	**Ciavarella, David 11-12-2013 (00:00:31)** 280:8 Q. And the reason you would want to know 280:9 the total number of complaints and the total 280:10 numbers of units distributed because you were 280:11 trying to see what the rate was at least based 280:12 on that data? 280:13 A. Yeah. I wanted to see what the rate 280:14 of reported events was. 280:15 Q. Because it was important from the 280:16 standpoint of whether or not this device may 280:17 have a unique design problem or may be 280:18 unnecessarily exposing patients to a risk that 280:19 you didn't realize existed with the product; 280:20 right?	05_14_18 Combo Jone V3.58
280:21 - 280:23	**Ciavarella, David 11-12-2013 (00:00:03)** 280:21 A. Well, I mean, eventually -- 280:22 Q. Is that yes or no? You can't answer 280:23 that yes or no?	05_14_18 Combo Jone V3.59
281:1 - 281:1	**Ciavarella, David 11-12-2013 (00:00:01)** 281:1 THE WITNESS: Well, yes.	05_14_18 Combo Jone V3.60
281:4 - 281:8	**Ciavarella, David 11-12-2013 (00:00:09)** 281:4 A. I mean, eventually that's the outcome 281:5 of my investigation, to try to get that 281:6 information. When I first asked -- asked for 281:7 it, it's just to put the number of events into 281:8 context.	05_14_18 Combo Jone V3.61
281:9 - 281:13	**Ciavarella, David 11-12-2013 (00:00:14)** 281:9 Q. The G -- then you state at the bottom: 281:10 "The G2 is a permanent filter; we also have one 281:11 (the SNF) that has virtually no complaints 281:12 associated with it. Why shouldn't doctors be 281:13 using that one rather than the G2?"	05_14_18 Combo Jone V3.62 CIAVARELLA33.1.1
281:14 - 281:15	**Ciavarella, David 11-12-2013 (00:00:02)** 281:14 You asked that question? 281:15 A. Uh-huh.	05_14_18 Combo Jone V3.63
281:16 - 283:19	**Ciavarella, David 11-12-2013 (00:03:07)** 281:16 Q. Why did you ask that question or is 281:17 the question pretty obvious?	05_14_18 Combo Jone V3.64

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281:18 A. Well, I mean, the question is obvious
281:19 in terms of I'm saying the G2 is a permanent
281:20 filter, the SNF is a permanent filter, we've had
281:21 very few complaints. It was a request for
281:22 information. I mean, I'd have to say it was
281:23 probably a -- in looking back on it now naive on
281:24 my part or lack of familiarity with the SNF
281:25 other than these tables and things which listed
282:1 reports. So --
282:2 Q. Well, you were suggesting that -- you
282:3 know, that if you have another device available
282:4 to you that was potentially safer and could
282:5 perform as well as or better than the G2, why
282:6 even sell the G2 right now until we resolve some
282:7 of these issues? Weren't you suggesting that?
282:8 A. Yeah, that's what I would conclude.
282:9 Q. And then you also ask: "Can you also
282:10 send me the total" complaint rates --
282:11 "complaints rate and MDR complaint rate for
282:12 SNF?"
282:13 You asked for that?
282:14 A. Right, because I didn't know very much
282:15 about the SNF. That's why I asked for the
282:16 rates. And I think that Bard has a process by
282:17 which all of the TrackWise complaints would be
282:18 sent to me by e-mail as well as several other
282:19 people, such as Mr. Ganser and Mr. Barry. So in
282:20 the past year or so I would see complaints
282:21 related to the Recovery filter, I would see
282:22 complaints related to the G2 filter, but I
282:23 didn't see any complaints related to the SNF.
282:24 So, you know, I had no idea how much
282:25 was sold, you know, what were the pros and cons
283:1 of using it, what were the different situations.
283:2 So that sort of explains my naive question but
283:3 also why I wanted to get more information about
283:4 the complaint rate for the Simon Nitinol.
283:5 Q. But you thought, at least as of
283:6 December 23rd, 2005, that a good exercise for
283:7 you as the medical affairs director would be to

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	283:8 see how the G2 in its short period on the market 283:9 compares from a complication and risk standpoint 283:10 to the Simon Nitinol filter? 283:11 A. Yeah, I wanted to -- I wanted to make 283:12 that comparison that -- I guess comparison's the 283:13 right word between the filters as part of my 283:14 review of the adverse event profile of the G2. 283:15 Q. Did someone prepare a report like that 283:16 for you? 283:17 A. You know, I don't remember. I don't 283:18 think that -- I don't think they would ignore 283:19 it, you know, my question.	clear
287:16 - 287:17	**Ciavarella, David 11-12-2013 (00:00:13)** 287:16 Q. So No. 35 will be your related health 287:17 hazard evaluation dated December 17, 2004.	05_14_18 Combo Jone V3.65 CIAVARELLA35.1.1
287:18 - 287:24	**Ciavarella, David 11-12-2013 (00:00:26)** 287:18 just confirm for us that that's the health 287:19 hazard evaluation that you prepared as part of 287:20 your duties as the medical director and within 287:21 which -- from which you gained information and 287:22 knowledge from having read Dr. Lehmann's report 287:23 dated December 15. 287:24 A. Yes.	05_14_18 Combo Jone V3.66 clear
293:11 - 293:23	**Ciavarella, David 11-12-2013 (00:00:44)** 293:11 Q. Isn't this like an early signal that 293:12 maybe there's more -- that the fracture problem 293:13 with the Recovery has not been fixed by the G2? 293:14 A. Right. And what I was trying to say 293:15 is it depends on a couple of things, including 293:16 the frequency. So these are all very small 293:17 numbers of reports and, therefore, it's hard to 293:18 know the true frequency. There are very wide 293:19 confidence intervals around these things. So 293:20 there would have to be a really powerful signal 293:21 before I would be led to conclude that -- or 293:22 even suggest that the G2 had a higher fracture 293:23 rate than Recovery.	05_14_18 Combo Jone V3.67
294:2 - 294:16	**Ciavarella, David 11-12-2013 (00:00:48)** 294:2 If you look at Page 2 -- well, it's 294:3 not Page 2. It's actually Page 3 of the	05_14_18 Combo Jone V3.68 clear

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	294:4 exhibit. And there's reference there to	
	294:5 Dr. Scott Trerotola. Do you know Dr. Trerotola?	CIAVARELLA36.3.1
	294:6 A. Yes, I've met him.	
	294:7 Q. He's Stanley Baum professor of	
	294:8 radiology, University of Pennsylvania, chief	
	294:9 interventional radiologist in Philadelphia.	
	294:10 Do you see that?	
	294:11 A. Yes.	
	294:12 Q. And does -- assuming that the G1A is,	clear
	294:13 in fact, the G2 filter, is Dr. Trerotola telling	
	294:14 the company as of February 2005 that he is still	CIAVARELLA36.3.2
	294:15 very concerned about fracture with that device?	
	294:16 A. Yeah	
294:18 - 294:20	**Ciavarella, David 11-12-2013 (00:00:07)**	05_14_18 Combo Jone V3.69
	294:18 THE WITNESS: It appeared that	clear
	294:19 that's what Janet Hudnall recorded from her	
	294:20 conversations with him.	
351:16 - 351:20	**Ciavarella, David 11-12-2013 (00:00:16)**	05_14_18 Combo Jone V3.70
	351:16 Q. Here's No. 39. No. 39 is a June --	
	351:17 July 9 HHE again authored by David Ciavarella	CIAVARELLA39.1.1
	351:18 regarding limb fractures of Recovery filter. Do	
	351:19 you see that?	
	351:20 A. I do.	
353:10 - 353:14	**Ciavarella, David 11-12-2013 (00:00:13)**	05_14_18 Combo Jone V3.71
	353:10 Q. so this deals with 17	CIAVARELLA39.1.6
	353:11 reports of limb fractures from the time period	
	353:12 July -- January 2002 through June 2004; is that	
	353:13 right?	
	353:14 A. Yes.	
353:22 - 354:3	**Ciavarella, David 11-12-2013 (00:00:32)**	05_14_18 Combo Jone V3.72
	353:22 Q. And you calculated from just this	CIAVARELLA39.1.7
	353:23 information, recognizing underreporting and such	
	353:24 but at least from the actual data that the	
	353:25 company had, that the fracture rate was 1 per	
	354:1 600 or 0.2 percent; is that right? Do you see	
	354:2 that?	
	354:3 A. Yes.	
354:18 - 356:11	**Ciavarella, David 11-12-2013 (00:02:04)**	05_14_18 Combo Jone V3.73
	354:18 Q. "In the second symptomatic case, the	CIAVARELLA39.1.8
	354:19 patient presented with sudden shortness of	

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354:20 breath and syncope."
354:21 Syncope is what?
354:22 A. Loss of consciousness.
354:23 Q. "Hemopericardium and cardiac
354:24 arrhythmia were diagnosed."
354:25 Do you see that?
355:1 A. I do.
355:2 Q. Those are serious potentially
355:3 catastrophic events; would you agree?
355:4 A. Yes.
355:5 Q. "A detached filter arm was noted in
355:6 the ventricular wall, and it was removed during
355:7 open heart surgery."
355:8 Did I read that correctly?
355:9 A. Yes.
355:10 Q. So what has been concluded here is
355:11 that one of these 17 fractures that were
355:12 reported carried with it symptoms and a
355:13 condition that could have very readily killed
355:14 the patient?
355:15 A. Yes.
355:16 Q. As a matter of fact, just having to
355:17 have open heart surgery puts the patient at risk
355:18 of death; right?
355:19 A. It does.
355:20 Q. And you further report that there were
355:21 20 arm fragments reported in 14 cases, meaning
355:22 there were actually more than one arm fragment
355:23 that fractured in some instances?
355:24 A. Yes.
355:25 Q. And in six of the patients the
356:1 detached arm migrated to the heart or lungs;
356:2 right?
356:3 A. Yes.
356:4 Q. And, by the way, the other fractures
356:5 that didn't migrate to the heart or lung or
356:6 cause, you know, hemopericardium and cardiac
356:7 arrhythmia and open heart surgery, the mere fact
356:8 that the limb fractured still put the patients
356:9 at the potential risk of those occurrences; am I

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	356:10 right about that? 356:11 A. Yes.	
356:16 - 356:19	**Ciavarella, David 11-12-2013 (00:00:07)** 356:16 Q. Now, down at the bottom: "The root 356:17 cause of the fractures has not been determined," 356:18 do you see where I am? 356:19 A. Yes.	05_14_18 Combo Jone V3.74
357:4 - 357:19	**Ciavarella, David 11-12-2013 (00:00:39)** 357:4 Q. Let me ask you, when you read that, 357:5 didn't you think to yourself we might have a 357:6 design issue with this product, it may not be 357:7 designed in the manner in which we intended and 357:8 expected it to perform from a fracture 357:9 standpoint? 357:10 A. Well, yes, I wrote the sentence 357:11 because I thought it might be relevant to the 357:12 root cause. 357:13 Q. Did you tell physicians -- by the way, 357:14 after the June HHE, did word go out, an eBlast, 357:15 information to salespeople giving them the 357:16 precise information about what the company was 357:17 seeing with other physicians' experiences with 357:18 the Recovery filter from the standpoint of 357:19 migrations	05_14_18 Combo Jone V3.75
357:20 - 357:23	**Ciavarella, David 11-12-2013 (00:00:06)** 357:20 A. I don't know. 357:21 Q. How about with respect to these 357:22 fractures? 357:23 A. Yeah, again, I don't know.	05_14_18 Combo Jone V3.76
358:2 - 358:6	**Ciavarella, David 11-12-2013 (00:00:14)** 358:2 Q. Do you know whether or not physicians 358:3 who were making risk/benefit assessments and 358:4 having informed consent discussions with their 358:5 patients might want to know whether or not there 358:6 have been 12 full filter migrations	05_14_18 Combo Jone V3.77
358:7 - 358:9	**Ciavarella, David 11-12-2013 (00:00:05)** 358:7 two resulting in 358:8 open heart surgery, they'd want to know that 358:9 before they decide to use that filter?	05_14_18 Combo Jone V3.78
358:12 - 358:13	**Ciavarella, David 11-12-2013 (00:00:03)**	05_14_18 Combo Jone V3.79

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	358:12 THE WITNESS: I don't know that 358:13 they weren't aware of it.	
358:15 - 358:20	**Ciavarella, David 11-12-2013 (00:00:24)** 358:15 Q. Well, I mean, how would they become 358:16 aware of them if the company didn't tell them? 358:17 A. Well, two things: One, they were 358:18 reported on the MAUDE database. Secondly, the 358:19 instructions for use contained information about 358:20 migrations and fractures.	05_14_18 Combo Jone V3.80
358:22 - 359:1	**Ciavarella, David 11-12-2013 (00:00:14)** 358:22 Do you know if 358:23 the company put out any type of information, 358:24 precise information, that describes the events 358:25 that you describe in your HHE in June of 2004? 359:1 A. Not that I recall.	05_14_18 Combo Jone V3.81
359:14 - 359:20	**Ciavarella, David 11-12-2013 (00:00:21)** 359:14 Q. On this team that is looking 359:15 at this -- these issues, migration and fracture 359:16 and the potential catastrophic event in 359:17 patients, is there anyone else on this team 359:18 that's a medical doctor besides David 359:19 Ciavarella? 359:20 A. No.	05_14_18 Combo Jone V3.82
359:24 - 360:6	**Ciavarella, David 11-12-2013 (00:00:23)** 359:24 Q. And let's look at the "Nature & 359:25 Seriousness of the Risk: The effect of filter 360:1 fracture is no" -- "The effect of filter 360:2 fracture is no discernible effect in most cases. 360:3 Serious injury or even sudden death may occur in 360:4 rare cases." 360:5 Right? 360:6 A. Yes.	05_14_18 Combo Jone V3.83 CIAVARELLA39.2.5
360:25 - 361:5	**Ciavarella, David 11-12-2013 (00:00:13)** 360:25 Q. "Likelihood of Occurrence of the 361:1 Problem," you wrote: No well-controlled trials 361:2 exist to answer this question definitively for 361:3 other filters. 361:4 You wrote that? 361:5 A. Yes.	05_14_18 Combo Jone V3.84 CIAVARELLA39.2.6
362:6 - 363:16	**Ciavarella, David 11-12-2013 (00:01:52)**	05_14_18 Combo Jone V3.85

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	362:6 Q. The very last sentence I believe on	
	362:7 Page 3 you wrote: "However, there is no way to	CIAVARELLA39.3.1
	362:8 predict which patients will develop this	
	362:9 complication. More frequent monitoring of the	CIAVARELLA39.4.1
	362:10 filter once placed may facilitate discovery of	
	362:11 abnormal placement (a possible but not proven	
	362:12 predisposing factor for fracture) or indeed of a	
	362:13 fractured filter, but could not prevent all	
	362:14 potential adverse events."	
	362:15 You wrote that; right?	
	362:16 A. I did.	
	362:17 Q. Did the company ever engage on a	clear
	362:18 recommendation to physicians either with a "Dear	
	362:19 Doctor" letter, a change in the IFU, eBlasts,	
	362:20 information given to their salespeople that it	
	362:21 was time for doctors to start monitoring the	
	362:22 Recovery filter once placed to see if they	
	362:23 could -- they might be able to find fractures?	
	362:24 A. I don't know.	
	362:25 Q. Wouldn't that have been a good idea	
	363:1 had the only doctor working on this case had	
	363:2 recommended it?	
	363:3 A. Not necessarily.	
	363:4 Q. But that was something that you	
	363:5 recommended in July of 2004 and, as far as you	
	363:6 know, the company did not do that; right?	
	363:7 A. I wouldn't say that I recommended it.	
	363:8 Q. Did you think it was a good idea?	
	363:9 A. I think I just put it out there as a	
	363:10 potential suggestion or something to think	
	363:11 about.	
	363:12 Q. Something that could potentially save	
	363:13 people from a fracture or device migrating to	
	363:14 the heart if you could catch it early in that	
	363:15 phase?	
	363:16 A. You know, my words are what they are.	
364:4 - 364:5	**Ciavarella, David 11-12-2013 (00:00:09)**	05_14_18 Combo Jone V3.86
	364:4 Q. Exhibit 40 is a February 15, 2006, HHE	CIAVARELLA40.1.1
	364:5 authored by Dr. Ciavarella	
364:14 - 365:2	**Ciavarella, David 11-12-2013 (00:00:51)**	05_14_18 Combo Jone V3.87

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	364:14 Q. And you report that -- and this is	CIAVARELLA40.1
	364:15 February 2006. The G2 had been on the market	
	364:16 for approximately, what, four or five months?	
	364:17 A. Yeah, probably. I don't remember	
	364:18 exactly.	
	364:19 Q. There had been ten reports of	CIAVARELLA40.1.3
	364:20 migration, one cephalad and nine caudal, as of	
	364:21 February 9, 2006; correct?	
	364:22 A. Yes.	
	364:23 Q. And your conclusion is that "the	
	364:24 Severity of this hazard is Critical, due to the	
	364:25 possibility of alteration of primary function as	
	365:1 a result of the migration events"; right?	
	365:2 A. Yes.	
366:1 - 366:19	**Ciavarella, David 11-12-2013 (00:00:53)**	05_14_18 Combo Jone V3.88
	366:1 You write that "...unlike literature	CIAVARELLA40.1.4
	366:2 reports, the migration events with the G2 filter	
	366:3 have been associated with a high percentage of	
	366:4 caudal" migration -- "migrations accompanied by	
	366:5 significant filter tilting and limb	
	366:6 displacement," and that there was a single case	
	366:7 of fatal pulmonary embolus, clinically	
	366:8 diagnosed, in a patient with a G2 filter	
	366:9 reported.	
	366:10 Do you see that?	
	366:11 A. I do.	
	366:12 Q. And did you write that in there	
	366:13 because of the way	
	366:14 the device tilted, it didn't prevent the	
	366:15 pulmonary embolism?	
	366:16 A. That was my potential possibility of	
	366:17 alteration of pulmonary function, meaning it	
	366:18 wouldn't stop a clot. So the reported rate of	
	366:19 pulmonary embolism is -- was relevant to that.	
369:2 - 369:6	**Ciavarella, David 11-12-2013 (00:00:13)**	05_14_18 Combo Jone V3.89
	369:2 "Likelihood of Occurrence of the Problem." You	CIAVARELLA40.2.1
	369:3 have the rate at 0.16 percent, meaning the	
	369:4 likelihood of there being a filter migration	
	369:5 with the G2, most of which would be caudal?	
	369:6 A. Uh-huh.	

05_14_18 Combo Jone V3-Civarella 11-12-14 Jones Trial Depo Designations V3

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369:18 - 369:24	**Ciavarella, David 11-12-2013 (00:00:17)** 369:18 Q. In fact, you even say after that 369:19 .16 percent that "The actual rate is probably 369:20 higher than this, due to the asymptomatic nature 369:21 of some of the migration events and because the 369:22 actual number of G2 filters implanted is very 369:23 probably less than the number distributed." 369:24 A. Yes.	05_14_18 Combo Jone V3.90 CIAVARELLA40.2.2
370:3 - 370:10	**Ciavarella, David 11-12-2013 (00:00:31)** 370:3 Q. And then you wrote "Likelihood of Harm 370:4 if the Problem Occurs:" "No serious injuries 370:5 have occurred, although the need for filter 370:6 removal and placement of alternative filters in 370:7 many cases points out the potential for harm if 370:8 a migration event is not discovered and 370:9 treated"; right? 370:10 A. Yes.	05_14_18 Combo Jone V3.91 CIAVARELLA40.2.3 CIAVARELLA40.3.1
370:19 - 370:23	**Ciavarella, David 11-12-2013 (00:00:12)** 370:19 Q. And then other alternatives available, 370:20 you agree that there are both alternative 370:21 permanent and retrievable IVC filters that exist 370:22 as an alternative to the G2? 370:23 A. Yes.	05_14_18 Combo Jone V3.92 clear

Plaintiffs Designations = 00:20:25
Defense Designations = 00:08:18
P & D Affimatives = 00:09:33
Total Time = 00:38:16

Documents Shown
BPVE
CIAVARELLA21
CIAVARELLA28
CIAVARELLA33
CIAVARELLA35
CIAVARELLA36
CIAVARELLA39
CIAVARELLA40

Exhibit E

Designation Run Report

DeFord_COMBO_0522_R05

DEFORD, John 06-02-2016

PL 00:06:02

DEF 00:23:43

Both 00:00:24

Total Time 00:30:09

DeFord_COMBO_0522_R05

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13:6 - 13:15	**DEFORD, John 06-02-2016 (00:00:23)** 13:6 Q. All right. Why don't you 13:7 explain then what your current position 13:8 is with the company? 13:9 A. Certainly. My -- I believe 13:10 this is probably prior to 2007, because 13:11 my title now is senior vice president for 13:12 science, technology, and clinical 13:13 affairs; and in 2007, the clinical 13:14 affairs piece was added to my 13:15 responsibilities.	DeFord_COMBO_0522_R05.1
14:21 - 15:20	**DEFORD, John 06-02-2016 (00:01:03)** 14:21 Q. So prior to Bard, what was 14:22 your experience in medical device 14:23 manufacturing? 14:24 A. I worked for a private 15:1 medical company, the Cook Group of 15:2 Companies, that's now called Cook 15:3 Medical, based in Indiana; and so I 15:4 worked in a number of their businesses 15:5 and was fortunate enough to be involved 15:6 in helping start some of their other 15:7 businesses. 15:8 Q. And per your C.V., you 15:9 actually began with Cook -- a Cook 15:10 company in 19 -- let's see what it was -- 15:11 1990, which was MED Institute, Inc.? 15:12 A. I was actually with MED 15:13 before that, after a Master's in -- 15:14 probably around 1986, and then I took a 15:15 leave of absence to complete a Ph.D. and 15:16 then came back to MED Institute in 1990. 15:17 Q. And your Ph.D. is in what 15:18 field? 15:19 A. Electrical and biomedical 15:20 engineering.	DeFord_COMBO_0522_R05.2
16:6 - 18:18	**DEFORD, John 06-02-2016 (00:02:33)** 16:6 Q. So beginning in 1990 16:7 until the time that you left in November 16:8 of 2001, so about 11 years, what type of	DeFord_COMBO_0522_R05.3

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16:9 roles did you have at the company that
16:10 would have educated you about the
16:11 operations of a medical device company?
16:12 A. Well, I started as a product
16:13 development engineer or project engineer
16:14 with MED Institute, primarily working on
16:15 class 3 devices, which were PMA devices,
16:16 and so then began interfacing -- MED
16:17 Institute was really a consulting
16:18 organization for the Cook Group of
16:19 Companies at that time, really doing
16:20 development work for the other Cook
16:21 Groups of Companies.
16:22 Q. And as you continued on with
16:23 the company, just per your -- your C.V.,
16:24 it appears that you received promotions
17:1 along the way; is that correct?
17:2 A. Yes.
17:3 Q. Okay.
17:4 And one of your promotions
17:5 was to go from general manager of Cook
17:6 Endovascular to senior vice president,
17:7 product development administration in
17:8 1999; is that correct?
17:9 A. That's correct.
17:10 Q. And as senior vice president
17:11 of product development at that point at
17:12 Cook, you were dealing with some
17:13 diagnostic and interventional products;
17:14 is that correct?
17:15 A. That's right.
17:16 Q. Did your work at that point
17:17 include vena cava filters?
17:18 A. To a limited extent, yes.
17:19 Q. Can you explain what you
17:20 mean by to a limited extent?
17:21 A. Certainly. Cook had
17:22 developed the Bird's Nest Vena Cava
17:23 Filter, and then that was actually going
17:24 through the development process and the

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	18:1 regulatory process while I was with the 18:2 company; and I had some peripheral 18:3 involvement, not -- not a great deal. 18:4 Similarly, the Guenther 18:5 Tulip Filter, which was developed in the 18:6 early '90s in Europe, was a product that 18:7 I was familiar with, although it wasn't 18:8 available in the U.S. 18:9 And then within diagnostic 18:10 and interventional products -- the way 18:11 Cook was structured at that time when I 18:12 received that promotion, that was a 18:13 position that was essentially general 18:14 manager for all of the radiology and 18:15 vascular products; and so diagnostic and 18:16 interventional really covered diagnostic 18:17 catheters, wires, interventional 18:18 products, which would include filters.	
20:22 - 21:5	**DEFORD, John 06-02-2016 (00:00:14)** 20:22 Q. Have you not yourself 20:23 conducted clinical research in 2000-2001 20:24 regarding the use of removable vena cava 21:1 filter for the prevention of pulmonary 21:2 embolus? 21:3 A. There was -- again, it was 21:4 research that was being conducted, yes, 21:5 and I was involved.	DeFord_COMBO_0522_R05.4
21:13 - 23:18	**DEFORD, John 06-02-2016 (00:01:56)** 21:13 Q. And that clinical research 21:14 that you did, explain that for us, if you 21:15 would, just tell us what the parameters 21:16 were of the research and who you 21:17 conducted it with and what it was for. 21:18 A. Sure. Well, my recollection 21:19 -- and it's been awhile, but my 21:20 recollection was that the Guenther Tulip 21:21 was technology being used in Europe. 21:22 There was a desire by the Cook 21:23 organization to bring that technology 21:24 into the U.S. with retrievability.	DeFord_COMBO_0522_R05.5

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22:1 And so there was research
22:2 that was being conducted in Europe and
22:3 evaluations, both animal and
22:4 retrospective human analysis, for
22:5 devices.
22:6 And at that particular time,
22:7 there was a concern about the length of
22:8 retrievability in the Guenther Tulip.
22:9 The view had been in those days that
22:10 probably 10 to 14 days was the
22:11 appropriate time period.
22:12 And so there were some
22:13 evaluations, as I recall, that were being
22:14 -- that we were conducting when I was at
22:15 Cook to determine retrievability and then
22:16 looking at the filters, once they were
22:17 retrieved, to see if there was
22:18 endothelial tissue that had adhered or
22:19 fibrous tissue growth, those types of
22:20 things.
22:21 Q. And what were the results of
22:22 your clinical research on that issue?
22:23 A. I don't remember all of the
22:24 details, but the results were that we
23:1 concluded there should be some additional
23:2 development of a next-generation
23:3 technology that would make it more
23:4 retrievable.
23:5 Q. Were there negative findings
23:6 in your clinical research regarding that
23:7 particular device and its ability to
23:8 retrieve --
23:9 A. I don't recall --
23:10 Q. -- be retrieved?
23:11 A. -- negative findings. I
23:12 think there were conformational findings
23:13 of the -- and, again, this is going back
23:14 a number of years, but there were some
23:15 conformational findings, as I recall,
23:16 that the device was not easy to remove.

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	23:17 And after it had been in for a period of 23:18 time, it became more difficult to remove.	
24:19 - 24:22	**DEFORD, John 06-02-2016 (00:00:07)** 24:19 You proceeded and progressed 24:20 at Cook to president and CEO; is that 24:21 correct? 24:22 A. That's correct.	DeFord_COMBO_0522_R05.6
35:13 - 35:22	**DEFORD, John 06-02-2016 (00:00:29)** 35:13 Q. What was your understanding 35:14 of the status of the IVC filter efforts 35:15 being made by Bard as of January 2004? 35:16 A. Well, my recollection going 35:17 back that time period was that -- I was 35:18 aware that Bard was working on some 35:19 really innovative technology that they 35:20 felt would allow retrievability of a 35:21 technology for long periods of time, 35:22 maybe even more than a year.	DeFord_COMBO_0522_R05.7
78:12 - 78:16	**DEFORD, John 06-02-2016 (00:00:09)** 78:12 Q. Would you agree that a 78:13 medical device manager -- excuse me -- 78:14 manufacturer must ensure that its device 78:15 is as safe as it can be before it sells 78:16 it to the public?	DeFord_COMBO_0522_R05.8
78:19 - 79:18	**DEFORD, John 06-02-2016 (00:00:50)** 78:19 THE WITNESS: I agree. I 78:20 think medical device manufacturers 78:21 should, to the best of their 78:22 ability, make devices that are 78:23 safe for the intended use. 78:24 BY MS. BOSSIER: 79:1 Q. And if there is no clinical 79:2 study that a medical device manufacturer 79:3 has to rely upon for safety when it puts 79:4 a device into the market, what is it 79:5 supposed to do to ensure safety of the 79:6 patients who receive the device? 79:7 A. Well, there's a lot of other 79:8 evaluation and testing that can be done 79:9 prior to clinical study, human clinical	DeFord_COMBO_0522_R05.9

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79:10 study. So there are animal studies with
79:11 animal vasculature -- for example, when
79:12 we're talking about filters, there's a
79:13 tremendous amount of bench testing that
79:14 existed then and has been augmented and,
79:15 you know, as knowledge has increased, all
79:16 of that new information has been taken
79:17 into account to develop new tests and new
79:18 ways to evaluate the technology.

102:19 - 103:4 **DEFORD, John 06-02-2016 (00:00:33)** DeFord_COMBO_0522_R05.10

102:19 So if you -- on this
102:20 document that I have shown you that ends
102:21 in the numbers 154050, there's some
102:22 further updates to that original meeting.
102:23 And if you look at the page
102:24 that ends in 059 --
103:1 A. 05 -- okay.
103:2 Q. -- the section that says
103:3 "Threshold Level for Migration" -- do you
103:4 see that? Up at the top?

103:8 - 103:16 **DEFORD, John 06-02-2016 (00:00:17)** DeFord_COMBO_0522_R05.11

103:8 Q. -- it says: The migration
103:9 threshold statement will be modified to
103:10 show the product assessment team will
103:11 consider placing the Recovery filters on
103:12 hold if a migration requiring surgical
103:13 intervention is reported during this
103:14 investigation. The determination will be
103:15 made quickly in cooperation with the
103:16 corporate product assessment team.

103:23 - 104:3 **DEFORD, John 06-02-2016 (00:00:11)** DeFord_COMBO_0522_R05.12

103:23 The process was that a threshold was set,
103:24 but my involvement in placing a product
104:1 on hold that -- from a process
104:2 perspective isn't something that I would
104:3 be involved with.

105:11 - 105:14 **DEFORD, John 06-02-2016 (00:00:07)** DeFord_COMBO_0522_R05.13

105:11 Q. And was the decision at the
105:12 time it was presented to keep the
105:13 Recovery filter on the market?

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	105:14 A. Yes.	
105:15 - 106:2	**DEFORD, John 06-02-2016 (00:00:27)**	DeFord_COMBO_0522_R05.14
	105:15 Q. And who ultimately made that 105:16 decision? 105:17 A. Well, it's a group decision, 105:18 if you will. The process, though, is one 105:19 where the division assessment team and 105:20 this group would have met and reviewed 105:21 all of the available information. 105:22 My recollection is, we also 105:23 brought in outside clinicians and 105:24 experts, had an expert panel to discuss 106:1 things that we were, again -- didn't 106:2 anticipate with the use of the device;	
120:7 - 120:13	**DEFORD, John 06-02-2016 (00:00:13)**	DeFord_COMBO_0522_R05.15
	120:7 That, as you can see by 120:8 these documents, Bard took a lot of time 120:9 and care trying to analyze each one of 120:10 these and understand the situations 120:11 behind them to see if there were specific 120:12 issues with the product or ways to 120:13 improve the product.	
120:16 - 120:17	**DEFORD, John 06-02-2016 (00:00:04)**	DeFord_COMBO_0522_R05.16
	120:16 but the truth is that Bard was 120:17 investigating this device	
120:18 - 120:22	**DEFORD, John 06-02-2016 (00:00:11)**	DeFord_COMBO_0522_R05.17
	120:18 and 120:19 undertook to put this entire plan into 120:20 place about this particular device with a 120:21 particular problem of migration 120:22 occurring	
121:1 - 121:3	**DEFORD, John 06-02-2016 (00:00:09)**	DeFord_COMBO_0522_R05.18
	121:1 At what point did Bard think 121:2 it was appropriate to take the device off 121:3 the market?	
121:12 - 122:6	**DEFORD, John 06-02-2016 (00:00:35)**	DeFord_COMBO_0522_R05.19
	121:12 The device is still adding 121:13 value. It couldn't stop a massive 121:14 thrombus, just like your seatbelt 121:15 can't stop a train from hitting	

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	121:16 you and destroying your car. This 121:17 thing was -- these kind of events 121:18 were beyond anything that Bard or 121:19 anyone in the industry to my 121:20 knowledge knew about. 121:21 And -- and so it was being 121:22 evaluated very vigorously. As you 121:23 can see by this documentation, we 121:24 were looking at it very closely, 122:1 very carefully, and trying to 122:2 understand every single event to 122:3 put the very best products on the 122:4 market and keep them as safe as 122:5 they possibly could be and keep 122:6 patients safe.	
129:3 - 129:5	**DEFORD, John 06-02-2016 (00:00:04)** 129:3 Q. Okay. So there were any 129:4 number of migrations -- and we could 129:5 count them all	DeFord_COMBO_0522_R05.20
129:6 - 129:16	**DEFORD, John 06-02-2016 (00:00:24)** 129:6 that occurred after 129:7 the original decision that if one more 129:8 happened, you all would -- Bard would put 129:9 it on hold and that didn't happen. 129:10 A. That's right. The original 129:11 decision was, if we had another one of 129:12 these incidents during the investigation, 129:13 the product would be put on hold; but as 129:14 more information came in and the 129:15 investigation continued, that decision 129:16 was changed.	DeFord_COMBO_0522_R05.21
129:23 - 130:3	**DEFORD, John 06-02-2016 (00:00:08)** 129:23 I think the risk to 129:24 patients was absolutely evaluated, 130:1 but the decision was made that the 130:2 product continued to add value and 130:3 shouldn't be placed on hold.	DeFord_COMBO_0522_R05.22
130:5 - 130:19	**DEFORD, John 06-02-2016 (00:00:30)** 130:5 Q. Well, if the product had 130:6 been placed on hold, then you would not	DeFord_COMBO_0522_R05.23

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	130:7 have had a retrievable filter on the 130:8 market. Right? 130:9 A. Well, that's -- that's 130:10 correct, but that -- that wasn't part of 130:11 the analysis, except that clinicians 130:12 wanted a device they could retrieve. It 130:13 wasn't a company decision, well, we're 130:14 not going to put it on hold because we're 130:15 selling a retrievable product. 130:16 It was the belief and our 130:17 continued belief that this product added 130:18 unique, special value and patients' lives 130:19 were being saved.	
133:7 - 133:10	**DEFORD, John 06-02-2016 (00:00:06)** 133:7 Q. Part of 133:8 a physician's decision to want to use a 133:9 device is to know what the risk and 133:10 benefits are. Right?	DeFord_COMBO_0522_R05.24
133:21 - 133:24	**DEFORD, John 06-02-2016 (00:00:04)** 133:21 First, there 133:22 was a tremendous amount of 133:23 discussion with clinicians 133:24 ongoing.	DeFord_COMBO_0522_R05.25
134:3 - 134:23	**DEFORD, John 06-02-2016 (00:00:37)** 134:3 This 134:4 wasn't happening in a vacuum. 134:5 There was a tremendous amount of 134:6 discussion in the medical 134:7 community about the technology, 134:8 about the use, and about these 134:9 cases, and about these situations. 134:10 So Bard wasn't withholding 134:11 this information. Although Bard 134:12 didn't in a broad way, you know, 134:13 send something out, Bard was 134:14 actively engaged with the FDA 134:15 discussing these situations, too, 134:16 and as you can see in all of this 134:17 documentation that we have, there 134:18 was a tremendous amount of	DeFord_COMBO_0522_R05.26

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	134:19 activity ongoing that involved 134:20 clinicians to evaluate the 134:21 technology, understand the 134:22 situations, and see what could be 134:23 done about it.	
137:1 - 137:5	**DEFORD, John 06-02-2016 (00:00:13)** 137:1 own -- in Bard's own documentation. You 137:2 know, when you talk about putting patient 137:3 safety first, one of the things that Bard 137:4 could have done at the time of the filter 137:5 migration	DeFord_COMBO_0522_R05.27
137:5 - 137:8	**DEFORD, John 06-02-2016 (00:00:07)** 137:5 in February 2004 was 137:6 place the product on hold, not wait one 137:7 more time. Right? 137:8 A. We certainly could have.	DeFord_COMBO_0522_R05.28
137:14 - 137:20	**DEFORD, John 06-02-2016 (00:00:16)** 137:14 Q. Okay. And if patient safety 137:15 was at the forefront of Bard's intentions 137:16 at that time, then putting the product on 137:17 hold and stepping back and ensuring that 137:18 the product was safe before it was sold 137:19 again would have been putting the patient 137:20 safety first; correct?	DeFord_COMBO_0522_R05.29
137:23 - 138:11	**DEFORD, John 06-02-2016 (00:00:25)** 137:23 THE WITNESS: I disagree 137:24 with that in that the evaluation, 138:1 as I recall, and the discussions 138:2 that we've had around filters was 138:3 that this technology was saving 138:4 many more lives than it was unable 138:5 to save. 138:6 And by -- and if we took it 138:7 off the market and did not have 138:8 that technology available, then 138:9 that would further increase the 138:10 risk to patients versus decrease 138:11 the risk to patients.	DeFord_COMBO_0522_R05.30
138:13 - 139:6	**DEFORD, John 06-02-2016 (00:00:39)** 138:13 Q. You had another product on	DeFord_COMBO_0522_R05.31

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	138:14 the market that was just as equally 138:15 capable, if not better, shown to be 138:16 better and more capable, of helping 138:17 patients than the Recovery filter; 138:18 correct? 138:19 A. I'm not -- we certainly had 138:20 another vena cava filter on the market, 138:21 the Simon Nitinol filter, very different 138:22 technology, certainly known to prevent 138:23 pulmonary embolism death, but didn't have 138:24 all of the features and benefits of 139:1 Recovery. 139:2 Q. Okay. I understand it 139:3 didn't have the bells and whistles of the 139:4 Recovery, but you are aware that it was a 139:5 much safer device than the Recovery 139:6 filter ended up being; correct?	
139:21 - 140:11	**DEFORD, John 06-02-2016 (00:00:27)** 139:21 The Simon Nitinol filter was 139:22 used in a very different class of 139:23 patients, as we came to learn, 139:24 from the Recovery filter. Simon 140:1 Nitinol primarily used in patients 140:2 that were -- where retrievability 140:3 wasn't a concern. 140:4 And so these were patients 140:5 that were -- terminal cancer 140:6 patients, for example, brain 140:7 cancer, has a high incidence of 140:8 thrombosis associated with it and 140:9 so trying to give patients quality 140:10 of life, other cancers, other 140:11 neoplasms.	DeFord_COMBO_0522_R05.32
140:23 - 141:5	**DEFORD, John 06-02-2016 (00:00:14)** 140:23 And so it's kind of trying 140:24 to compare the technologies that 141:1 were really designed for different 141:2 kind of application. Same goal of 141:3 preventing fatal pulmonary 141:4 embolism, but used in a different	DeFord_COMBO_0522_R05.33

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	141:5 type of situation.	
141:7 - 142:5	**DEFORD, John 06-02-2016 (00:00:37)** 141:7 Q. The Recovery was originally 141:8 designed for permanent placement; 141:9 correct? 141:10 A. Sure. 141:11 Q. So it was intended to be 141:12 permanent. 141:13 A. That's right, with the 141:14 retrievability option. 141:15 Q. Correct. So the Simon 141:16 Nitinol filter was a permanent filter; 141:17 correct? 141:18 A. That's correct. 141:19 Q. So when Bard was weighing do 141:20 we take this off the market, do we keep 141:21 it on the market, and you're telling me 141:22 that Bard decided, well, we need to go 141:23 save all these patients from all these 141:24 massive pulmonary embolisms that are 142:1 killing people all over the country, you 142:2 had a device that was already doing that. 142:3 Right? You had the Simon Nitinol filter. 142:4 Right? 142:5 A. Yes --	DeFord_COMBO_0522_R05.34
142:8 - 142:9	**DEFORD, John 06-02-2016 (00:00:01)** 142:8 THE WITNESS: -- yes, we had 142:9 the Simon Nitinol filter --	DeFord_COMBO_0522_R05.35
218:9 - 218:14	**DEFORD, John 06-02-2016 (00:00:18)** 218:9 Q. At this point in December of 218:10 '04, are you aware of anything Bard did 218:11 to study the Recovery filter to determine 218:12 whether or not there was safety -- to 218:13 determine whether or not it was safe to 218:14 be implanted in patients?	DeFord_COMBO_0522_R05.36
218:17 - 219:5	**DEFORD, John 06-02-2016 (00:00:17)** 218:17 THE WITNESS: There were a 218:18 lot of activities and we talked a 218:19 little bit about that this 218:20 morning, but there were ongoing	DeFord_COMBO_0522_R05.37

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	218:21 series of evaluations and new 218:22 tests being developed and 218:23 additional information and all the 218:24 matrix that we talked about 219:1 before. 219:2 So there was a lot of 219:3 analysis ongoing to better 219:4 understand the technology and its 219:5 use.	
219:7 - 220:21	**DEFORD, John 06-02-2016 (00:01:21)** 219:7 Q. So my question was, did Bard 219:8 undertake any studies -- 219:9 A. Yes. 219:10 Q. Okay. 219:11 A. There were a host of 219:12 internal studies, bench tests. My 219:13 recollection is, again, all of that was 219:14 ongoing. 219:15 Q. Can you point to anything 219:16 definitive that occurred, any -- any 219:17 specific testing that you're aware of 219:18 where you participated in with regard to 219:19 Recovery that would have -- that would 219:20 have -- Recovery specific -- the specific 219:21 Recovery filter we're talking about right 219:22 now that would have supported a statement 219:23 by Bard that the Recovery filter was safe 219:24 for implantation in patients? 220:1 A. Again, there was the initial 220:2 testing that was done and then ongoing 220:3 testing. Trying to pull out a specific 220:4 test, 12 years later, I don't recall, but 220:5 I'm sure that there -- I mean, my 220:6 recollection is, there was a lot of 220:7 activity ongoing and a lot of testing and 220:8 discussion and analysis that was taking 220:9 place. 220:10 Q. There was certainly nothing 220:11 published by Bard or any of its key 220:12 opinion leaders or researchers on this	DeFord_COMBO_0522_R05.38

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	220:13 issue -- 220:14 A. I'm not aware that there 220:15 were publications of some of the tests 220:16 that were developed and so on. I believe 220:17 there were presentations by clinicians. 220:18 Again, none of this was happening in a 220:19 vacuum. There was a lot of ongoing 220:20 discussion, but I'm not aware that Bard 220:21 published anything,	
226:14 - 227:5	**DEFORD, John 06-02-2016 (00:00:27)** 226:14 Q. Well, in September of 2015, 226:15 on the video we just listened to, you 226:16 stated: They, being the IVC filters, are 226:17 implanted by physicians only after a 226:18 careful assessment of the risk and 226:19 benefits for the individual patient and 226:20 they should be removed after protection 226:21 from pulmonary embolism is no longer 226:22 needed. 226:23 Correct? 226:24 A. Correct. 227:1 Q. And that's what you said in 227:2 that video; correct? 227:3 A. Yes. 227:4 Q. Now, that is not something 227:5 that you told the doctors in -- in	DeFord_COMBO_0522_R05.39
227:9 - 227:10	**DEFORD, John 06-02-2016 (00:00:01)** 227:9 Q. in the IFU. 227:10 A. No.	DeFord_COMBO_0522_R05.66
227:12 - 227:14	**DEFORD, John 06-02-2016 (00:00:06)** 227:12 And yet you knew in -- Bard 227:13 knew in 2004 the need for retrieving an 227:14 IVC filter.	DeFord_COMBO_0522_R05.40
227:17 - 228:16	**DEFORD, John 06-02-2016 (00:00:43)** 227:17 THE WITNESS: I -- I don't 227:18 understand -- and to the extent I 227:19 understand the question, I guess 227:20 I'd say no. IVC filters were 227:21 designed, so the Recovery was 227:22 designed to be retrievable. We	DeFord_COMBO_0522_R05.41

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	227:23 thought and still believe that 227:24 that added significant value to 228:1 the patient with the ability to 228:2 retrieve it. 228:3 But we didn't specifically 228:4 say, you must retrieve it or you 228:5 should retrieve it, although my 228:6 belief is that that was common 228:7 knowledge: That this is a 228:8 retrievable device. If you don't 228:9 need it anymore, why are you 228:10 leaving it in? It's designed 228:11 specifically so you can take it 228:12 out. 228:13 BY MS. BOSSIER: 228:14 Q. Well, it obviously wasn't 228:15 common knowledge because the rates of 228:16 retrieval were so terribly low; correct?	
228:19 - 230:4	**DEFORD, John 06-02-2016 (00:00:57)** 228:19 THE WITNESS: I disagree. I 228:20 don't think it was a fact of not 228:21 being common knowledge. I think 228:22 it was more a function of the way 228:23 these patients are treated. 228:24 So at that particular time 229:1 in history, interventional 229:2 radiologists were the primary 229:3 placers. Interventional 229:4 radiologists don't usually track 229:5 the patient. The patient is 229:6 referred to them for a filter 229:7 placement by a surgeon or some 229:8 other clinician, oncologist, for 229:9 example. They place it and at 229:10 that particular time, those 229:11 patients wouldn't necessarily know 229:12 to go back to the radiologist for 229:13 retrieval. 229:14 And so it kind of got lost 229:15 in the system. It wasn't until	DeFord_COMBO_0522_R05.42

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	229:16 later that better systems were 229:17 devised to track those patients to 229:18 be able to call them and get them 229:19 back and have the product 229:20 retrieved. 229:21 So I don't think it was a 229:22 matter of not common knowledge 229:23 that the products were retrievable 229:24 and could be retrieved or even 230:1 should be retrieved. It was a 230:2 matter of those patients weren't 230:3 in a pool where they could be 230:4 found to have them retrieved.	
230:9 - 230:14	**DEFORD, John 06-02-2016 (00:00:15)** 230:9 Where we are right now is, 230:10 in 2004, December 2004, Bard was aware of 230:11 the risk associated with allowing a 230:12 retrievable filter to remain in dwelling 230:13 for an extended period of time, was it 230:14 not?	DeFord_COMBO_0522_R05.43
230:21 - 231:17	**DEFORD, John 06-02-2016 (00:00:40)** 230:21 THE WITNESS: I'd like to 230:22 say yes or no, but it's more 230:23 complicated than that in that 230:24 there was a body of evidence, 231:1 small body of evidence, suggesting 231:2 that -- that filters should be 231:3 removed. This was back in 1998. 231:4 That led to the development of 231:5 some of the retrievable devices 231:6 and so I don't think that -- at 231:7 that time, my recollection is, at 231:8 that time, there wasn't a sense 231:9 that the devices must be retrieved 231:10 or should be retrieved, but could 231:11 be retrieved. 231:12 And then clinicians 231:13 understood that this technology, 231:14 because of its retrievable nature, 231:15 was such that if the risk was no	DeFord_COMBO_0522_R05.44

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	231:16 longer there, you could take it 231:17 out.	
237:5 - 237:22	**DEFORD, John 06-02-2016 (00:00:44)** 237:5 Q. The issue of advising 237:6 physicians to monitor patients who have 237:7 been implanted with the IVC filter, that 237:8 is not a new notion to Bard, is it? 237:9 A. I mean, it's not an 237:10 immediate notion. I mean, I think any 237:11 time a device is used, there should be 237:12 monitoring of that technology regardless 237:13 of where it's used, and so that's 237:14 independent of vena cava filter. 237:15 And, again, I would view 237:16 that as sort of common knowledge that 237:17 you'd want to watch these devices, you 237:18 know, whether it's a knee implant, a hip 237:19 implant, a stent placed anywhere in the 237:20 body, or a vena cava filter. 237:21 So the -- certainly the idea 237:22 of monitoring is not new.	DeFord_COMBO_0522_R05.45
237:23 - 238:4	**DEFORD, John 06-02-2016 (00:00:15)** 237:23 Q. And it is certainly 237:24 something that Bard could have warned 238:1 physicians about in 2004; correct? 238:2 A. We could have, that's right. 238:3 There's a lot of things that we could 238:4 have done that we didn't -- either didn't	DeFord_COMBO_0522_R05.46
238:5 - 238:12	**DEFORD, John 06-02-2016 (00:00:15)** 238:5 think it was -- you know, it was 238:6 something that was common knowledge that 238:7 we thought didn't need to be done or it 238:8 didn't cross our mind as something that 238:9 needed to be put into a document. 238:10 So I don't think it was a 238:11 matter of intentionally choosing to leave 238:12 things out.	DeFord_COMBO_0522_R05.47
238:23 - 239:5	**DEFORD, John 06-02-2016 (00:00:18)** 238:23 Q. And so it is important for a 238:24 medical device manufacturer, in fact it's	DeFord_COMBO_0522_R05.49

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	239:1 essential for a medical device 239:2 manufacturer, to advise a physician of 239:3 all the known risks and benefits of the 239:4 use of their device; is that correct? 239:5 A. Certainly, yes.	
239:6 - 239:12	**DEFORD, John 06-02-2016 (00:00:24)** 239:6 Q. And by not -- and wouldn't a 239:7 doctor need to know the frequency and 239:8 severity of the migration issues and the 239:9 filter fracture issues that Bard knew 239:10 about in December of 2004 in order to 239:11 adequately assess the risk and benefits 239:12 for using this device on their patients?	DeFord_COMBO_0522_R05.50
239:16 - 240:22	**DEFORD, John 06-02-2016 (00:01:10)** 239:16 There were ongoing 239:17 clinician and public discussions in 239:18 public forums and meetings and 239:19 conferences and with doctors during this 239:20 entire time period. 239:21 So none of this was 239:22 happening in a vacuum and it's akin to, 239:23 you know, leaving a message for a family 239:24 member, there's a whole lot more 240:1 background behind that than is just in 240:2 it. 240:3 And so I think there was 240:4 knowledge of the issues that were 240:5 associated with retrievable vena cava 240:6 filters and the issues that we were 240:7 seeing here, again, with the continued 240:8 belief that these products were saving 240:9 lives, but as we got more information, we 240:10 needed to share the details of that 240:11 information here. 240:12 So I'm not sure that 240:13 specific rate information at a snapshot 240:14 in time necessarily would change their 240:15 decision-making process; and that because 240:16 there was so much discussion going on in 240:17 the medical community, this was sort of	DeFord_COMBO_0522_R05.51

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	240:18 the -- another level of detail coming 240:19 from the company. 240:20 Q. But it was not as detailed 240:21 of information as the company actually 240:22 had in its possession; correct?	
241:1 - 241:18	**DEFORD, John 06-02-2016 (00:00:35)** 241:1 THE WITNESS: No, it 241:2 certainly wasn't. I mean, there's 241:3 always a decision on how much 241:4 information is appropriate and 241:5 gives the right level of detail. 241:6 You know, we could have sent 241:7 volumes and volumes of information 241:8 and all the tests and matrices and 241:9 those kind of things. 241:10 At the time, we felt, and in 241:11 conjunction with FDA -- again, 241:12 this was not happening in a 241:13 vacuum. There were lots of 241:14 discussions with the U.S. Food and 241:15 Drug Administration to discuss the 241:16 level of detail that was to be 241:17 provided, and this was I think 241:18 informative and appropriate.	DeFord_COMBO_0522_R05.52
242:23 - 244:1	**DEFORD, John 06-02-2016 (00:00:57)** 242:23 Q. And then perhaps anything 242:24 they may have learned in the literature 243:1 or at different conferences or other 243:2 types of events, maybe learning events 243:3 with other colleagues; is that right? 243:4 A. Certainly. And then the 243:5 physician panel that was pulled together 243:6 and those kind of events, which were also 243:7 -- those physicians were then 243:8 disseminating additional information to 243:9 their colleagues and so on. 243:10 Q. Tell me about the physician 243:11 panel. 243:12 A. So I don't remember the time 243:13 period, but over the course of the	DeFord_COMBO_0522_R05.53

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	243:14 discussion of the analysis of some of the 243:15 events, I recall that a physician panel 243:16 was convened to discuss the adverse 243:17 events -- all the details were provided, 243:18 is my recollection -- and get their input 243:19 on risks, benefits. 243:20 And, again, this was in my 243:21 view one of the important things that, 243:22 you know, continued to point to the value 243:23 of the technology and the importance of 243:24 continuing to keep it available to 244:1 patients.	
278:21 - 279:4	**DEFORD, John 06-02-2016 (00:00:26)** 278:21 Q. When you told members of the 278:22 public in your video that your -- that 278:23 Bard's IVC filters had been -- had 278:24 undergone testing and were evaluated by 279:1 the FDA, did you intend to tell the 279:2 public that the FDA's evaluation was 279:3 somehow akin to it saying that the 279:4 devices were safe?	DeFord_COMBO_0522_R05.54
279:7 - 279:19	**DEFORD, John 06-02-2016 (00:00:25)** 279:7 THE WITNESS: You know, I 279:8 think FDA does evaluate even 279:9 510(k) devices based on safety and 279:10 efficacy and the information 279:11 available, although they would 279:12 say, and it's my understanding 279:13 they would say, that safety and 279:14 efficacy are not their primary 279:15 review process in the 510(k). 279:16 But their overall function 279:17 as the Food and Drug 279:18 Administration is to ensure safe 279:19 and effective devices and drugs.	DeFord_COMBO_0522_R05.55
279:21 - 279:24	**DEFORD, John 06-02-2016 (00:00:11)** 279:21 Q. But don't they rely upon the 279:22 medical device manufacturer for -- for a 279:23 lot of the information that they have, 279:24 especially safety?	DeFord_COMBO_0522_R05.56

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280:4 - 280:12	**DEFORD, John 06-02-2016 (00:00:17)** 280:4 THE WITNESS: -- they rely 280:5 on the medical device manufacturer 280:6 for most all of the information, 280:7 as we're the ones who do the 280:8 development and the testing and, 280:9 by and large, have more sort of 280:10 technical knowledge of the 280:11 products and technologies than the 280:12 FDA would.	DeFord_COMBO_0522_R05.57
280:14 - 281:4	**DEFORD, John 06-02-2016 (00:00:32)** 280:14 Q. And you understand and you 280:15 would agree with me that the 510(k) 280:16 process is not an opportunity for the FDA 280:17 to evaluate a medical device for safety 280:18 or efficacy. 280:19 A. I'm not -- I don't agree 280:20 with that. They can. They do. They ask 280:21 questions. They can ask for additional 280:22 detail or clinical studies or other 280:23 information if they deem that that's 280:24 appropriate, and they also set guidance 281:1 documents and standards for testing and 281:2 evaluation for a host of medical devices, 281:3 and I believe there are guidance 281:4 documents for filters.	DeFord_COMBO_0522_R05.58
281:15 - 281:24	**DEFORD, John 06-02-2016 (00:00:23)** 281:15 Q. The 281:16 FDA's position is that when it clears a 281:17 device through the 510(k) process, it's 281:18 not saying that it -- that device is safe 281:19 or effective, is it? 281:20 A. I don't believe -- yeah, I 281:21 don't think they take the -- the strict 281:22 safety/efficacy -- I think their comment 281:23 to the public is that they -- that that's 281:24 not their primary function.	DeFord_COMBO_0522_R05.59
281:24 - 282:3	**DEFORD, John 06-02-2016 (00:00:06)** 281:24 But I do 282:1 think they would say that safety and	DeFord_COMBO_0522_R05.60

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	282:2 effectiveness is a part of their 282:3 evaluation process.	
282:12 - 282:20	**DEFORD, John 06-02-2016 (00:00:23)** 282:12 Q. The -- part of the 510(k) 282:13 process allows a medical device 282:14 manufacturer to rely upon a predecessor 282:15 product or predicate product for 282:16 clearance of a new device if that new 282:17 device is substantially equivalent; isn't 282:18 that correct? 282:19 A. Yes, that's my 282:20 understanding.	DeFord_COMBO_0522_R05.61
318:18 - 318:21	**DEFORD, John 06-02-2016 (00:00:08)** 318:18 Q. I mean, Bard knew that it 318:19 was important to monitor devices that 318:20 were remaining in dwelling for long 318:21 periods of time, didn't it?	DeFord_COMBO_0522_R05.62
318:24 - 319:20	**DEFORD, John 06-02-2016 (00:00:47)** 318:24 THE WITNESS: Well, first 319:1 off, I think the body of knowledge 319:2 on monitoring vena cava filters in 319:3 particular was advancing at that 319:4 particular time period because, 319:5 again, the history was, only 319:6 permanent devices usually placed 319:7 in patients where you weren't 319:8 concerned about retrieval, often 319:9 terminal patients, and so now 319:10 we're into a different class. 319:11 And so although I'd say 319:12 there was general knowledge to 319:13 monitor any implants, today, as in 319:14 2004, the body of knowledge 319:15 specific to filters was advancing 319:16 and I don't think there was the 319:17 same kind of sense or knowledge 319:18 base that we have today about the 319:19 importance of monitoring the 319:20 devices.	DeFord_COMBO_0522_R05.63
322:13 - 322:20	**DEFORD, John 06-02-2016 (00:00:16)**	DeFord_COMBO_0522_R05.64

DeFord_COMBO_0522_R05

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	322:13 Q. I'm showing you another 322:14 document, Dr. DeFord, that is another 322:15 health hazard evaluation and this one is 322:16 dated February 15, 2006, again from David 322:17 Ciavarella, Dr. Ciavarella, re: G2 322:18 Inferior Vena Cava Filter migration. 322:19 Do you see that? 322:20 A. Yes.	
325:17 - 326:3	**DEFORD, John 06-02-2016 (00:00:34)** 325:17 Q. Do you know whether or not 325:18 Bard ever advised physicians about this 325:19 increased risk of caudal migration? 325:20 A. I'm not aware of specific 325:21 communication directly to physicians 325:22 concerning caudal migration. I know 325:23 there were discussions about it, and I 325:24 know again it was an ongoing discussion 326:1 in the medical community and that this 326:2 was a new or more frequent event with the 326:3 G2 than it was seen before.	DeFord_COMBO_0522_R05.65

PL = 00:06:02
DEF = 00:23:43
Both = 00:00:24
Total Time = 00:30:09

Exhibit F

Designation Run Report

Greer 08-11-14 Jones Trial Depo Designations V2

Greer, Jason 08-11-2014

PlaintiffsDesignations 00:06:18

Defense Designations 00:02:13

Total Time 00:08:31

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5:21 - 5:24	**Greer, Jason 08-11-2014 (00:00:06)** 5:21 Q. Good morning, Mr. Greer. 5:22 A. Morning. 5:23 Q. Have you ever given a deposition before? 5:24 A. Yes.	05_11_18 Jones Combo V2.1
22:6 - 22:11	**Greer, Jason 08-11-2014 (00:00:31)** 22:6 Q. When did you first start working for Bard? 22:7 A. It was -- I think it was towards the end of '99. 22:8 Q. Okay. And when did you leave Bard? 22:9 A. It was sometime in 2007. 22:10 Q. Okay. What was your first position at Bard? 22:11 A. It was a territory manager, sales rep.	05_11_18 Jones Combo V2.2
22:12 - 22:16	**Greer, Jason 08-11-2014 (00:00:15)** 22:12 Q. And was that the Lone Star territory? 22:13 A. No. That was my region when I was a regional sales 22:14 manager. My territory when I had it was Memphis. It didn't 22:15 really have a territory name. It may have been called Memphis. 22:16 I don't know.	05_11_18 Jones Combo V2.3
23:7 - 23:13	**Greer, Jason 08-11-2014 (00:00:27)** 23:7 Q. what point were you promoted to a district 23:8 manager? 23:9 A. It would have to be -- 2006. Yeah. 2005 time frame. 23:10 2004. 2004, 2005. 23:11 Q. What I saw was very late 2004. Does that seem 23:12 right? 23:13 A. That's probably right. That makes sense.	05_11_18 Jones Combo V2.4
23:23 - 24:7	**Greer, Jason 08-11-2014 (00:00:21)** 23:23 Q. While you were a district manager, your 23:24 district was called the Lone Star State district, though, 23:25 right? 24:1 A. Yes. 24:2 Q. Okay. 24:3 A. Well, I believe it was -- yeah. I can't remember if 24:4 it was a period when I had Texas and part of Tennessee where we 24:5 weren't Lone Star, and then there was a period when I just had 24:6 Memphis and Texas, but I think it's all semantics. I had 24:7 Texas.	05_11_18 Jones Combo V2.5
59:22 - 59:24	**Greer, Jason 08-11-2014 (00:00:08)** 59:22 Q. Now, were you ever made aware that according to 59:23 Bard's own policy and procedure, the Recovery filter had an	05_11_18 Jones Combo V2.6

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	59:24 unacceptable risk level and required product correction?	
60:1 - 60:5	**Greer, Jason 08-11-2014 (00:00:22)**	05_11_18 Jones Combo V2.7
	60:1 A. I was aware that, as with every product I've ever 60:2 sold, that there are opportunities to develop and improve the 60:3 product, especially when the rates are more in the median of 60:4 accepted rates, that you work to improve them, and there's 60:5 constantly engineers working on improving current products.	
60:6 - 60:9	**Greer, Jason 08-11-2014 (00:00:06)**	05_11_18 Jones Combo V2.8
	60:6 Q. When you were at 60:7 Bard, were you ever made aware that the Recovery filter 60:8 according to Bard's own policy and procedure had an 60:9 unacceptable risk level?	
60:11 - 60:13	**Greer, Jason 08-11-2014 (00:00:12)**	05_11_18 Jones Combo V2.9
	60:11 A. There was -- there was -- the question was raised by 60:12 sales people when I was a sales manager, and the response of 60:13 the company was always that the rates were acceptable.	
115:12 - 115:18	**Greer, Jason 08-11-2014 (00:00:28)**	05_11_18 Jones Combo V2.10
	115:12 it's -- it's in defense, in the defensive position. I don't 115:13 know how Mark did it. You would have to ask him. But I can 115:14 only tell you when I read that, I would think, in a defensive 115:15 position, where a competitor is bringing up the subject that 115:16 the purpose of the MAUDE database is not to bash the other 115:17 filters, which I previously stated, but to illustrate there's 115:18 not a perfect filter and there's ongoing reporting database.	
145:15 - 145:15	**Greer, Jason 08-11-2014 (00:00:02)**	05_11_18 Jones Combo V2.11 GREER.1
	145:15 Q. Let's mark this as Exhibit No. 7, I believe.	
146:5 - 147:9	**Greer, Jason 08-11-2014 (00:01:26)**	05_11_18 Jones Combo V2.12 GREER.1.1
	146:5 Q. Do you agree that this is an e-mail from you dated 146:6 March 16, 2006, to Janet Hudnall? 146:7 A. Yes. 146:8 Q. Okay. See this paragraph here I'm pointing to? 146:9 A. (Reviews.) Yeah. 146:10 Q. Okay. Can you read that e-mail to the jury, please? 146:11 A. Sure. "I was thinking how far we've come in a year 146:12 as" -- 146:13 Q. I'm sorry. Start at the beginning, "By the way." 146:14 A. By the way, you know what I was thinking about 146:15 today. I was thinking about how far we've come in a year as 146:16 far as filter problems. I know we are having a few problems, 146:17 but do you freaking remember what it was like a year ago? Do	GREER.1.2

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	146:18 you remember what it was like two years ago? I don't know if 146:19 it can get any worse. You weathered the storm as well as 146:20 anyone -- anyone could have. If you do decide to interview 146:21 for new positions, you better document what you did because I 146:22 don't think there are many better business case studies for a 146:23 terrible situation that was held together with scotch tape, 146:24 smoke, mirrors, crying, et cetera. You should be pretty proud 146:25 of yourself. 147:1 Q. In this e-mail you are referring to Bard's filters. 147:2 Right? 147:3 A. Yeah. 147:4 Q. And at that time, it was the Recovery filter that you 147:5 were referring to. Correct? 147:6 A. Yes. 147:7 Q. Okay. And you are stating that in 2004, the 147:8 situation was bad; in 2005, it was terrible. Right? 147:9 A. That's correct. It was -- it was rough.	clear
147:20 - 148:2	**Greer, Jason 08-11-2014 (00:00:35)** 147:20 Q. In this e-mail are you stating that 147:21 Janet Hudnall held together the Recovery filter situation in 147:22 2004 and 2005 with scotch tape, smoke, mirrors, crying, 147:23 et cetera? 147:24 A. I would say that we all take patient complications 147:25 very hard. And then it was an incredibly emotional time where 148:1 our customers were emotional. And holding all of that together 148:2 was -- was difficult.	05_11_18 Jones Combo V2.13
148:18 - 148:22	**Greer, Jason 08-11-2014 (00:00:17)** 148:18 In this e-mail, are you 148:19 stating that -- to Janet Hudnall, that in 2004 and 2005 she 148:20 held together a terrible situation regarding the Recovery 148:21 filter with scotch tape, smoke, mirrors, crying, et cetera? 148:22 A. That's what is written there, yes, sir.	05_11_18 Jones Combo V2.14 GREER.1.3
170:3 - 170:6	**Greer, Jason 08-11-2014 (00:00:09)** 170:3 Q. Do you have any reason to believe that you would have 170:4 ever warned a physician that the Recovery filter had a higher 170:5 reported failure rate than other devices? 170:6 A. No. I don't think so.	05_11_18 Jones Combo V2.15 clear
173:7 - 173:8	**Greer, Jason 08-11-2014 (00:00:05)** 173:7 Q. That's Exhibit No. 12. It was No. 13 to your 173:8 prior deposition.	05_11_18 Jones Combo V2.16

Page/Line	Source	ID
174:10 - 175:9	**Greer, Jason 08-11-2014 (00:01:28)** 174:10 Q. Do you agree that this is an e-mail from you 174:11 dated July 16, 2005 to at this point your sales 174:12 representatives working under you? 174:13 A. Yes. 174:14 Q. Okay. And you copy Robert DeLeon and Janet Hudnall? 174:15 A. Uh-huh. 174:16 Q. In this e-mail, are you giving your salespeople 174:17 direction on how to respond if a physician is made concerned by 174:18 someone using the MAUDE data base? 174:19 A. This is an e-mail -- yes, how to deal with -- when 174:20 one of your competitors brings forward the MAUDE database, 174:21 that's correct. 174:22 Q. Look at the second-to-last bullet point on the second 174:23 page. See where it says, If you are doing them and you are 174:24 concerned, may I suggest the safest filter on the market that 174:25 has been on the market the longest time in its current form, 175:1 dot, dot, dot, the Simon Nitinol? You see that? 175:2 A. Uh-huh. 175:3 Q. Did you write that? 175:4 A. Yes. 175:5 Q. Okay. Are you telling your sales force that the 175:6 Simon Nitinol filter is the safest filter on the market? 175:7 A. I'm telling them that -- I'm suggesting that the 175:8 safest filter on the market has been on the market for the 175:9 longest time in its current form is the Simon Nitinol.	05_11_18 Jones Combo V2.17
176:10 - 176:11	**Greer, Jason 08-11-2014 (00:00:05)** 176:10 Q. In this e-mail are you stating that the Simon 176:11 Nitinol filter is the safest filter on the market at this time?	05_11_18 Jones Combo V2.18
176:13 - 176:23	**Greer, Jason 08-11-2014 (00:00:36)** 176:13 A. I'm saying if you read the -- I noticed you 176:14 highlighted this and you haven't highlighted before. But if 176:15 you want to read this, the sentences leading up to that, it 176:16 makes it very important. But it says, "If your doctor wants a 176:17 permanent filter, it's a fantastic permanent filter, and here's 176:18 why. It's been on the market longer than any other filter in 176:19 its current form." 176:20 Q. Sir, where do you see "permanent filter" in that 176:21 bullet point? 176:22 A. I don't have bullet point. I was explaining the	05_11_18 Jones Combo V2.19

Page/Line	Source	ID
	176:23 statement.	
176:24 - 177:5	**Greer, Jason 08-11-2014 (00:00:13)** 176:24 Q. I'm asking you what is in this statement. You said 176:25 it says "permanent filter." It don't say "permanent filter." 177:1 A. Did you ask me what I meant or what I said? 177:2 Q. Okay. Sir -- 177:3 A. I don't -- the word "permanent," obviously isn't in 177:4 there. I mean, do you think I'm going to say that a word is in 177:5 there that is not?	05_11_18 Jones Combo V2.20
177:12 - 177:23	**Greer, Jason 08-11-2014 (00:00:28)** 177:12 Q. Are you also telling the jury that this statement is 177:13 not making the representation that the Simon Nitinol filter 177:14 will give you the greatest chance of reducing your 177:15 complications? 177:16 A. It's a permanent filter. A permanent filter is not 177:17 for everybody. 177:18 Q. Sir, it doesn't say "permanent filter" in this bullet 177:19 point, does it? 177:20 A. Well, I didn't -- I never called the Simon Nitinol -- 177:21 the Simon Nitinol permanent filter and the Recovery the 177:22 retrievable filter. It was just referred to -- people -- it 177:23 was inferred that it was a permanent filter.	05_11_18 Jones Combo V2.21

PlaintiffsDesignations = 00:06:18
Defense Designations = 00:02:13
Total Time = 00:08:31

Documents Shown
GREER

Exhibit G

Designation Run Report

Hudnall 11-03-13 Jones Trial Designations V3

Hudnall, Janet 11-01-2013

Plaintiffs Designations 00:23:58

DefenseDesignations 00:03:49

P & D Designations 00:00:23

Total Time 00:28:10

Page/Line	Source	ID
5:20 - 5:22	**Hudnall, Janet 11-01-2013 (00:00:03)** 5:20 Q. Could you state your full name for the 5:21 record, please? 5:22 A. Janet Hudnall.	05_16_18 Combo Jones V3.1
17:4 - 17:20	**Hudnall, Janet 11-01-2013 (00:00:33)** 17:4 Q. when you were 17:5 at Bard, in addition to your salary, was there any 17:6 incentive or bonus or -- 17:7 A. There was a bonus program. 17:8 Q. Okay. How did the bonus program work at 17:9 Bard? 17:10 A. 25 percent of the annual salary. 17:11 Q. Based on what kind of performance? 17:12 A. Based on -- based on meeting company or 17:13 the divisional objectives, as well as personal 17:14 objectives, for the year. 17:15 Q. Okay. And was it -- was that across the 17:16 product line of Bard, C.R. Bard? 17:17 A. What does that mean? 17:18 Q. In other words, it -- it was a 17:19 performance-based bonus, right? 17:20 A. Performance-based bonus, yes.	05_16_18 Combo Jones V3.2
21:2 - 21:4	**Hudnall, Janet 11-01-2013 (00:00:04)** 21:2 Q. When did you first become involved in any 21:3 capacity with IVC filters? 21:4 A. 2002.	05_16_18 Combo Jones V3.3
35:1 - 35:10	**Hudnall, Janet 11-01-2013 (00:00:31)** 35:1 Q. Distinguish for me the difference between 35:2 sales and marketing at Bard. 35:3 A. The difference between sales and marketing 35:4 is salespeople go out and get orders and get -- and 35:5 actually -- actually execute the transaction to get 35:6 the revenue. 35:7 Marketing people set the strategy for the 35:8 product line and are responsible for the 35:9 commercialization of the product and transfer of 35:10 the product to the salespeople.	05_16_18 Combo Jones V3.4
35:16 - 35:19	**Hudnall, Janet 11-01-2013 (00:00:10)** 35:16 Q. You have also been described as the 35:17 liaison between the company and its customers; is	05_16_18 Combo Jones V3.5

Page/Line	Source	ID
	35:18 that a fair representation of what you did?	
	35:19 A. Myself among others, yes.	
36:4 - 36:7	**Hudnall, Janet 11-01-2013 (00:00:11)**	05_16_18 Combo Jones V3.6
	36:4 Q. Do you know if the sales representatives	
	36:5 or the sales managers were incentivized by reaching	
	36:6 particular sales volumes or quotas?	
	36:7 A. Yes, yes.	
36:8 - 36:9	**Hudnall, Janet 11-01-2013 (00:00:01)**	05_16_18 Combo Jones V3.81
	36:8 Q. Do you know how that worked?	
	36:9 A. No.	
36:10 - 36:11	**Hudnall, Janet 11-01-2013 (00:00:04)**	05_16_18 Combo Jones V3.82
	36:10 Q. It was based on a quota or a volume?	
	36:11 A. Probably. That's how it usually works.	
44:14 - 44:15	**Hudnall, Janet 11-01-2013 (00:00:03)**	05_16_18 Combo Jones V3.7
	44:14 Q. Do you know what a 510 application is?	
	44:15 A. A 510(k)?	
44:18 - 45:9	**Hudnall, Janet 11-01-2013 (00:00:31)**	05_16_18 Combo Jones V3.8
	44:18 Q. Yeah, 510(k) application is?	
	44:19 A. Yes.	
	44:20 Q. What is it?	
	44:21 A. It's a premarket authorization to	
	44:22 commercialize a device based on the fact that it's	
	44:23 substantially equivalent to a device that's already	
	44:24 on the market.	
	44:25 Q. And -- and what did you -- what did you	
	45:1 understand substantial equivalence to mean?	
	45:2 A. Substantial equivalence means that it's	
	45:3 not any worse than the device that's out there	
	45:4 previously.	
	45:5 Q. In other words, that it's -- it's -- when	
	45:6 you say "not any worse," it's at least as safe --	
	45:7 A. Correct.	
	45:8 Q. -- and at least as effective, right?	
	45:9 A. Right.	
53:12 - 53:20	**Hudnall, Janet 11-01-2013 (00:00:24)**	05_16_18 Combo Jones V3.9
	53:12 Q. And as a marketing person, didn't	
	53:13 you learn somewhere along the line that the	
	53:14 benefit/risk decisions about using a medical device	
	53:15 or any product with -- with a patient is that	
	53:16 within the exclusive province of the physician and	

Page/Line	Source	ID
	53:17 the patient?	
	53:18 A. You're right. You're right about that.	
	53:19 And it's the company's responsibility to give them	
	53:20 the information required to make that assessment.	
54:3 - 54:8	**Hudnall, Janet 11-01-2013 (00:00:18)**	05_16_18 Combo Jones V3.10
	54:3 well, first of all, before I move on to that, the	
	54:4 reason doctors have to know the risks and the	
	54:5 benefits of a product is so that they can make	
	54:6 informed decisions about a variety of therapeutic	
	54:7 options they may have for a patient, correct?	
	54:8 A. Correct.	
55:16 - 56:8	**Hudnall, Janet 11-01-2013 (00:00:34)**	05_16_18 Combo Jones V3.11
	55:16 Q. Well, for example, I mean, you -- you have	
	55:17 a sales force to go out and -- and discuss fair --	
	55:18 in a fair, balanced way the benefits and risks of	
	55:19 products, right, while you were at Bard?	
	55:20 A. Yes.	
	55:21 Q. And you know what fair balance means?	
	55:22 A. Yes.	
	55:23 Q. That means you can't go in and just talk	
	55:24 about all the wonderful things the product can do,	
	55:25 right?	
	56:1 A. Yes.	
	56:2 Q. You have to talk about what some of the	
	56:3 downside risks are, right?	
	56:4 A. Yes.	
	56:5 Q. And sometimes, that you have to expose	
	56:6 risks that are -- that may even put you at a	
	56:7 disadvantage with a competitor?	
	56:8 A. Sure.	
56:15 - 56:23	**Hudnall, Janet 11-01-2013 (00:00:20)**	05_16_18 Combo Jones V3.12
	56:15 Q. Well, in other words, you shouldn't hold	
	56:16 back information you have about risks just to	
	56:17 maintain a competitive advantage over someone when	
	56:18 you know that's the kind of risk a physician needs	
	56:19 to know for him to do a benefit risk analysis?	
	56:20 A. Sure. Of course not.	
	56:21 Q. And the message needs to be honest at all	
	56:22 times?	
	56:23 A. Yes.	

Page/Line	Source	ID
56:24 - 57:12	**Hudnall, Janet 11-01-2013 (00:00:44)** 56:24 Q. And part of your position as a marketing 56:25 person at Bard, in addition to you knowing what 57:1 type of things a physician might like about a 57:2 product for purposes of using it, it was your job 57:3 to also understand what are some of the things 57:4 physicians would like to know about relative risks 57:5 and the severity and frequency of risks to 57:6 determine whether or not to use the product, right? 57:7 A. Yes. 57:8 Q. And in a competitive market, it would be 57:9 wrong to downplay your risks against a competitor 57:10 when you had -- if you had information that your 57:11 risks were actually greater than the competitor; 57:12 would you agree with that?	05_16_18 Combo Jones V3.13
57:14 - 57:16	**Hudnall, Janet 11-01-2013 (00:00:06)** 57:14 THE WITNESS: If we had information that 57:15 the risks that -- if the risks were actually 57:16 greater, yes, it would be wrong.	05_16_18 Combo Jones V3.14
67:9 - 67:13	**Hudnall, Janet 11-01-2013 (00:00:24)** 67:9 Q. And by the way, has Bard ever done a study 67:10 that you know of that established that you can 67:11 safely remove a Recovery or G2 filter after a year? 67:12 A. That specific endpoint? No. You have to 67:13 leave it open.	05_16_18 Combo Jones V3.15
91:2 - 91:4	**Hudnall, Janet 11-01-2013 (00:00:06)** 91:2 Q. BY MR. LOPEZ: Okay. I have marked this 91:3 as Exhibit 20, which was Exhibit 15 to the 91:4 deposition that you gave three years ago.	05_16_18 Combo Jones V3.16
92:17 - 92:18	**Hudnall, Janet 11-01-2013 (00:00:02)** 92:17 Q. Have you seen this document recently? 92:18 A. Yes.	05_16_18 Combo Jones V3.17
93:9 - 93:10	**Hudnall, Janet 11-01-2013 (00:00:02)** 93:9 Q. Who prepared this document, do you know? 93:10 A. I did.	05_16_18 Combo Jones V3.18
94:5 - 94:12	**Hudnall, Janet 11-01-2013 (00:00:22)** 94:5 Q. And then here, this -- this was on the -- 94:6 Page 2 of 16, there's a section called "Market 94:7 Customer/Device." 94:8 Do you see that?	05_16_18 Combo Jones V3.19

Page/Line	Source	ID
	94:9 A. Yes. 94:10 Q. What's the purpose of that section? 94:11 A. Description of the market landscape, 94:12 what's going on in the market.	
94:13 - 94:19	**Hudnall, Janet 11-01-2013 (00:00:12)** 94:13 Q. Was Recovery already on the market at this 94:14 time? 94:15 A. No. 94:16 Q. Even -- even -- not even in a permanent? 94:17 A. I don't believe so. Each project is 94:18 supposed to get a product opportunity appraisal 94:19 done at the very beginning.	05_16_18 Combo Jones V3.20
94:20 - 95:24	**Hudnall, Janet 11-01-2013 (00:01:13)** 94:20 Q. what is this figure up here in 94:21 the upper left-hand corner, 25-point? 94:22 A. Net present value. 94:23 Q. But what is that? What is net present 94:24 value? 94:25 A. I am going to show -- I am going to be 95:1 embarrassed, an MBA -- MBA who can't really 95:2 describe what NPV is. The net present value of the 95:3 project as it stands today. 95:4 Q. Was that, like, a forecast? Is that 95:5 another way -- 95:6 A. It's -- it's a -- it's a combination of 95:7 the revenues as well as the costs. So it's sort of 95:8 what the -- the project is worth to us today. 95:9 Q. So are you looking at this from the 95:10 standpoint of if -- you know, if we do -- if we do 95:11 launch this, that it has the potential of doing 95:12 that -- those types of numbers annually? 95:13 A. Yes, yes. 95:14 Q. Okay. And then this is the budget. 95:15 You -- you must have done an analysis of what it 95:16 would cost to -- what, to get it through the 510(k) 95:17 process? 95:18 A. That is done -- that is done by R&D, but 95:19 yes. 95:20 Q. Okay. And then it describes the market, 95:21 right, market description? And then you knew here	05_16_18 Combo Jones V3.21

Page/Line	Source	ID
	95:22 that the current US IVC filter market was 95:23 $114 million, right? 95:24 A. Yes.	
99:1 - 100:5	**Hudnall, Janet 11-01-2013 (00:01:28)** 99:1 Q. And it talks about, see here, it says, 99:2 "Bard's Simon Nitinol filter has maintained its 99:3 market share position at 11 to 12 percent"? 99:4 A. Yes. 99:5 Q. So in other words, even though some of 99:6 these other products were coming on the market and 99:7 affecting the sales of Greenfield, the Simon 99:8 Nitinol filter seemed to be maintaining its market 99:9 share? 99:10 A. Yes. 99:11 Q. And then you wrote, "However, we will need 99:12 to introduce a new device with clear advantages in 99:13 order to maintain and grow our IVC market business 99:14 moving forward." You wrote that? 99:15 A. Yes, I did. 99:16 Q. And what did you mean by that? 99:17 A. Just what it says. 99:18 Q. In other words, if you wanted to capture 99:19 more than 11 or 12 percent of the market share in 99:20 the IVC filter arena, you'd have to come up with a 99:21 new device? 99:22 A. New device, yes. 99:23 Q. With clear advantages? 99:24 A. Yes. 99:25 Q. And what -- what do you mean by 100:1 "advantages"? 100:2 A. Advantages -- advantages, it's hard to 100:3 explain things that are so basic. "Advantages" 100:4 meaning lower profile, retrievable, just next 100:5 generation devices.	05_16_18 Combo Jones V3.22 HUDNALL20.4.1 HUDNALL20.4.2 clear
100:14 - 100:23	**Hudnall, Janet 11-01-2013 (00:00:15)** 100:14 Q. By the way, what does "lower profile" 100:15 mean? 100:16 A. It's smaller in diameter. 100:17 Q. Smaller in diameter? 100:18 A. Yes.	05_16_18 Combo Jones V3.23

Page/Line	Source	ID
	100:19 Q. Why would -- why would that be an 100:20 advantage? 100:21 A. Because you want a smaller entry site so 100:22 that you have a smaller wound in your -- in your 100:23 skin.	
101:4 - 101:9	**Hudnall, Janet 11-01-2013 (00:00:13)** 101:4 Q. And then you wrote, "Users can be swayed 101:5 by ease of use, low profile, and aggressive 101:6 marketing, even in the absence of solid clinical 101:7 history and in spite of documented negative 101:8 clinical experiences"? 101:9 A. Yes.	05_16_18 Combo Jones V3.24 HUDNALL20.4.6
101:10 - 101:22	**Hudnall, Janet 11-01-2013 (00:00:42)** 101:10 Q. And how did you learn that? 101:11 A. Through the Cordis TrapEASE experience. 101:12 Q. And so if you were to -- to develop a 101:13 product that was -- had -- was ease of use -- or 101:14 that was easy to use and had a low profile that you 101:15 just talked about, and even if it had documented 101:16 negative clinical experiences, aggressive marketing 101:17 could still make that a successful product? 101:18 A. What I was talking about here is that 101:19 these are the market conditions I am describing. 101:20 This is not a plan of action here. These are the 101:21 market conditions. So users can be swayed. They 101:22 have been swayed.	05_16_18 Combo Jones V3.25 clear
108:2 - 108:8	**Hudnall, Janet 11-01-2013 (00:00:23)** 108:2 Q. as a marketer and the person in charge 108:3 of marketing the Recovery and the G2 -- the G2 and 108:4 the Recovery line of products until you left, it 108:5 would be wrong and unethical to, if you had a 108:6 negative clinical experience with those devices, to 108:7 just use aggressive marketing to continue to sell 108:8 them, right?	05_16_18 Combo Jones V3.26
108:10 - 108:11	**Hudnall, Janet 11-01-2013 (00:00:07)** 108:10 THE WITNESS: It would be wrong if we were 108:11 providing a lot of risks without any benefits, yes.	05_16_18 Combo Jones V3.27
108:13 - 108:17	**Hudnall, Janet 11-01-2013 (00:00:11)** 108:13 If there was documented 108:14 negative clinical experience, for you to ignore	05_16_18 Combo Jones V3.28

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	108:15 that and just use aggressive marketing to --	
	108:16 A. To ignore it would be wrong.	
	108:17 Q. Okay. And to continue to sell it?	
108:19 - 108:22	**Hudnall, Janet 11-01-2013 (00:00:07)**	05_16_18 Combo Jones V3.29
	108:19 THE WITNESS: To ignore it would be wrong.	
	108:20 Q. BY MR. LOPEZ: And to not maybe share that	
	108:21 with physicians would be wrong, too, correct?	
	108:22 A. Yes.	
108:23 - 109:2	**Hudnall, Janet 11-01-2013 (00:00:18)**	05_16_18 Combo Jones V3.30
	108:23 Q. And out of this, we have also on Page 6 of	HUDNALL20.8.1
	108:24 10, these are -- this -- well, why don't you	
	108:25 describe what this is?	
	109:1 A. Just a projection of how much you think	
	109:2 you can sell.	
109:16 - 109:25	**Hudnall, Janet 11-01-2013 (00:00:17)**	05_16_18 Combo Jones V3.31
	109:16 Q. You thought you could grow	HUDNALL20.8.2
	109:17 from 3 percent to 25 percent --	
	109:18 A. Yes.	
	109:19 Q. -- market share, and that the units could	
	109:20 go from 3,000 in the first year to 41,000 in year	
	109:21 five, right?	
	109:22 A. Yes.	
	109:23 Q. In fact, you did -- actually did better	clear
	109:24 than that, didn't you?	
	109:25 A. Great. I don't know. I don't know.	
115:4 - 115:9	**Hudnall, Janet 11-01-2013 (00:00:13)**	05_16_18 Combo Jones V3.32
	115:4 Q. So you prepared the	
	115:5 document, you signed -- you sent it off to these	
	115:6 folks, and the people signed off on it, meaning	
	115:7 what?	
	115:8 A. Signing off means they have reviewed it	
	115:9 and approved it, or agree with it.	
115:24 - 116:1	**Hudnall, Janet 11-01-2013 (00:00:05)**	05_16_18 Combo Jones V3.33
	115:24 Q. And how were you involved in preparing for	
	115:25 the launch?	
	116:1 A. I -- I was the architect of the launch.	
120:25 - 121:14	**Hudnall, Janet 11-01-2013 (00:00:28)**	05_16_18 Combo Jones V3.34
	120:25 And there's other things that could	
	121:1 happen, with the vena cava being where it's	
	121:2 located, if this device isn't built as robustly and	

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	121:3 as safely as possible, are there not? 121:4 A. Like what? 121:5 Q. Well, I don't know. You -- you don't 121:6 know? 121:7 A. You must have some sort of an answer in 121:8 mind when you're asking a question. 121:9 Q. Well, I was hoping you would -- you would 121:10 know what those are. 121:11 A. Well, why don't you -- why don't you tell 121:12 me, and I'll give you yes or no answers. 121:13 Q. You'd rather do it that way? 121:14 A. Yeah.	
127:11 - 127:19	**Hudnall, Janet 11-01-2013 (00:00:14)** 127:11 Q. As a marketer -- 127:12 A. Yes. 127:13 Q. -- of a pharmaceutical or medical device? 127:14 A. Don't know anything about pharmaceuticals. 127:15 Q. Of a medical device, you need to know what 127:16 fair balance means, don't you? 127:17 A. I do. 127:18 Q. And you -- and just give me your 127:19 description of fair balance?	05_16_18 Combo Jones V3.35
127:21 - 127:22	**Hudnall, Janet 11-01-2013 (00:00:02)** 127:21 THE WITNESS: I -- why do I need to give 127:22 that to you?	05_16_18 Combo Jones V3.36
129:6 - 129:9	**Hudnall, Janet 11-01-2013 (00:00:09)** 129:6 Q. BY MR. LOPEZ: My question is: What does 129:7 "fair balance" mean to you when it comes to 129:8 marketing a medical device? You don't know? 129:9 A. You -- I guess I don't. I guess I don't.	05_16_18 Combo Jones V3.37
136:13 - 136:20	**Hudnall, Janet 11-01-2013 (00:00:27)** 136:13 Q. Did you ever receive any data during the 136:14 entire time that the Recovery was on the market 136:15 which revealed any statistics about how many -- of 136:16 how many patients were saved from a pulmonary 136:17 embolism going to their heart by having a Recovery 136:18 filter in them, any statistics? 136:19 A. That's theoretically the same number of 136:20 units that -- that were implanted.	05_16_18 Combo Jones V3.38
138:9 - 138:24	**Hudnall, Janet 11-01-2013 (00:00:28)**	05_16_18 Combo Jones V3.39

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	138:9 You wouldn't be able to give a number for 138:10 that, would you? 138:11 A. Nobody can, and we certainly couldn't. 138:12 Q. What do you mean "nobody can"? 138:13 A. How would you know that? 138:14 Q. Well, I don't know. I mean, how would 138:15 you -- you tell me. 138:16 A. Nobody can know that. 138:17 Q. How could -- 138:18 A. Unless you -- unless you take every 138:19 patient who has ever had a filter placed and you 138:20 put realtime imaging on them, 24 hours a day, every 138:21 single day, and see what's going on with any kind 138:22 of thrombus that's forming in their legs and their 138:23 hips and you see and you visualize it, there's no 138:24 way to know that.	
139:19 - 139:23	**Hudnall, Janet 11-01-2013 (00:00:16)** 139:19 that's not what I'm asking. I am asking you just 139:20 pure data. There's no data that exists that shows 139:21 that in a Recovery filter, there was a thrombus 139:22 that was stopped by a Recovery or G2 filter from 139:23 going beyond the filter?	05_16_18 Combo Jones V3.40
139:25 - 140:6	**Hudnall, Janet 11-01-2013 (00:00:08)** 139:25 Q. BY MR. LOPEZ: Right? 140:1 A. No one -- no one else, either. 140:2 Q. So is the answer am I right? 140:3 A. Are you right? 140:4 Q. Yeah. 140:5 A. If you need to hear that, yes, you are 140:6 right.	05_16_18 Combo Jones V3.41
143:4 - 143:7	**Hudnall, Janet 11-01-2013 (00:00:11)** 143:4 Q. Caval trapping and caval patency; that was 143:5 a feature that you were selling as a benefit of the 143:6 product? 143:7 A. Yes.	05_16_18 Combo Jones V3.42 _1_HUDNALL21.1.1
143:8 - 143:21	**Hudnall, Janet 11-01-2013 (00:00:42)** 143:8 Q. what's the significance of 143:9 self-centering? 143:10 A. So the device is a conical device that has 143:11 a single layer coming in from the below. Just	05_16_18 Combo Jones V3.83 HUDNALL21.1.4

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	143:12 because of the mechanical forces, it has to tilt.	
	143:13 Because this device had a delivery system that had	
	143:14 some specific features on it, had a better chance	
	143:15 of deploying in a centered manner upon deployment.	
	143:16 Q. And -- and centering is important because	clear
	143:17 tilting could cause some problems in a filter,	
	143:18 right?	
	143:19 A. I think they later found out -- well,	
	143:20 theoretically, yes. A -- a single-level filter	
	143:21 which tilts could potentially have issues.	
154:8 - 154:10	**Hudnall, Janet 11-01-2013 (00:00:03)**	05_16_18 Combo Jones V3.43
	154:8 Q. Then the next one is Exhibit 22.	_1_HUDNALL22.1
	154:9 (Reporter marked Exhibit No. 22 for	
	154:10 identification.)	
154:18 - 155:19	**Hudnall, Janet 11-01-2013 (00:01:11)**	05_16_18 Combo Jones V3.44
	154:18 Q. what	
	154:19 would you call this piece?	
	154:20 A. It's the same thing. It's a screen shot	
	154:21 of a web page.	
	154:22 Q. Okay. And again, this would contain the	clear
	154:23 same information that you would have in a brochure	
	154:24 that you would leave with a doctor or what you	
	154:25 would put in a journal?	
	155:1 A. The journal wouldn't contain this much	
	155:2 information, but yes, it would be in a brochure.	
	155:3 Q. Okay. So this is the -- by the way, the	
	155:4 G2 is just the next -- they call it a G2 because	
	155:5 it's the next generation of Recovery, correct?	
	155:6 A. Correct.	
	155:7 Q. And according to this marketing piece, one	HUDNALL22.1.2
	155:8 of the advantages -- some of the advantages of the	
	155:9 G2 were increased migration resistance, improved	
	155:10 centering, and enhanced fracture resistance.	
	155:11 A. Yes.	
	155:12 Q. Compared to what?	
	155:13 A. Compared to the previous generation.	
	155:14 Q. Okay. And again, you have this comment	_1_HUDNALL22.1.1
	155:15 about secure fixation?	
	155:16 A. Yes.	
	155:17 Q. And was it true that the G2 was designed	clear

Page/Line	Source	ID
	155:18 because of issues with migration resistance, 155:19 centering issues, and some fractures?	
155:21 - 156:1	**Hudnall, Janet 11-01-2013 (00:00:09)**	05_16_18 Combo Jones V3.45
	155:21 THE WITNESS: It's an improvement to the 155:22 previous device, yes. 155:23 Q. BY MR. LOPEZ: But it was designed 155:24 specifically because of migration resistance 155:25 issues, centering issues, and fracture issues with 156:1 the recovery?	
156:3 - 156:5	**Hudnall, Janet 11-01-2013 (00:00:03)**	05_16_18 Combo Jones V3.46
	156:3 THE WITNESS: Because of? 156:4 Q. BY MR. LOPEZ: Yeah. 156:5 A. Yeah, you could call it that.	
156:9 - 156:13	**Hudnall, Janet 11-01-2013 (00:00:22)**	05_16_18 Combo Jones V3.47
	156:9 Then the next document is -- I am going to 156:10 give you this as one big document, although it 156:11 appears to be more than one document, but they are 156:12 consecutively Bates stamped, and this is going to 156:13 be -- am I on 23?	_1_HUDNALL23.1
157:13 - 157:18	**Hudnall, Janet 11-01-2013 (00:00:17)**	05_16_18 Combo Jones V3.48
	157:13 Q. And however, the messages are -- with 157:14 respect to migration resistance, improved 157:15 centering, and fracture resistance are the same, 157:16 right? 157:17 Do you see that? 157:18 A. Yes.	HUDNALL23.1.2
166:6 - 166:11	**Hudnall, Janet 11-01-2013 (00:00:11)**	05_16_18 Combo Jones V3.49
	166:6 Q. If it did not have increased migration 166:7 resistance when compared to your competitive 166:8 products and you had data to suggest that, would 166:9 that be misleading? 166:10 A. If we had data to suggest that it would be 166:11 misleading, yes.	clear
166:12 - 166:14	**Hudnall, Janet 11-01-2013 (00:00:07)**	05_16_18 Combo Jones V3.50
	166:12 Q. So if the G2 was cleared for 166:13 retrievability indication in January of 2008, 166:14 this -- this is -- this would be your piece, right?	
166:17 - 166:17	**Hudnall, Janet 11-01-2013 (00:00:01)**	05_16_18 Combo Jones V3.51
	166:17 THE WITNESS: Yes.	
178:4 - 178:5	**Hudnall, Janet 11-01-2013 (00:00:02)**	05_16_18 Combo Jones V3.52

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	178:4 MR. LOPEZ: What number are we on, please?	
	178:5 THE REPORTER: 24.	
178:9 - 178:19	**Hudnall, Janet 11-01-2013 (00:00:36)**	05_16_18 Combo Jones V3.53
	178:9 Q. BY MR. LOPEZ: This is a February 27,	HUNDNALL 24RAUCH.1.1
	178:10 2004, email from David Rauch to Janet Hudnall. Did	
	178:11 you see this before the deposition?	
	178:12 A. Yes.	
	178:13 Q. Who is David Rauch?	HUNDNALL 24RAUCH.1
	178:14 A. He, I think, at the time was a -- he used	
	178:15 to be a sales rep. I think at the time he was --	
	178:16 was a sales trainer.	
	178:17 Q. And then this was -- the subject here is	HUNDNALL 24RAUCH.1.2
	178:18 "Case for caval centering"?	
	178:19 A. Uh-huh.	
179:1 - 180:15	**Hudnall, Janet 11-01-2013 (00:01:22)**	05_16_18 Combo Jones V3.54
	179:1 He's commenting on a training piece.	
	179:2 Would that be one of your training pieces, right?	
	179:3 A. Maybe.	
	179:4 Q. "Having said that, however, I must	HUNDNALL 24RAUCH.1.3
	179:5 strongly caution against emphasizing Recovery's	
	179:6 ability to center in the cava to the point where it	
	179:7 is the focus of product positioning."	
	179:8 A. Uh-huh.	
	179:9 Q. "We knew very little about long-term	
	179:10 clinical performance of this" -- "of this device	
	179:11 when we launched it. After a year of	
	179:12 commercialization, there are still many questions	
	179:13 that need to be answered."	
	179:14 A. Uh-huh.	
	179:15 Q. "One thing that we do know, however, is	
	179:16 that Recovery does not always stay centered in the	
	179:17 cava."	
	179:18 A. Uh-huh.	
	179:19 Q. Right?	
	179:20 A. Yep.	
	179:21 Q. And that even says here at the bottom, "I	HUNDNALL 24RAUCH.1.4
	179:22 think for a piece like this, it's critical to	
	179:23 clearly reference the entire body of the text so	
	179:24 that the reader can differentiate between what is	
	179:25 documented in the literature and what is	

Page/Line	Source	ID
	180:1 anecdotal/opinion."	
	180:2 A. Uh-huh.	
	180:3 Q. And then you answered -- I'm sorry,	
	180:4 then -- that was -- no, actually, that was from you	
	180:5 to David?	
	180:6 A. Right.	
	180:7 Q. And then you wrote back to David, "Thank	HUNDNALL 24RAUCH.1.5
	180:8 you for your valuable feedback. You are right.	
	180:9 Now that we have more experience with Recovery, the	
	180:10 positioning and tilt resistance should probably be	
	180:11 downplayed."	
	180:12 A. Uh-huh.	
	180:13 Q. You saw this before the deposition; you	clear
	180:14 knew I was going to probably ask you questions	
	180:15 about this, right?	
180:17 - 180:17	**Hudnall, Janet 11-01-2013 (00:00:01)**	05_16_18 Combo Jones V3.55
	180:17 THE WITNESS: Possibly.	
181:24 - 182:7	**Hudnall, Janet 11-01-2013 (00:00:23)**	05_16_18 Combo Jones V3.56
	181:24 Q. Okay. "Should probably be played down."	
	181:25 So if -- if a doctor were to ask Mr. Rauch, or	
	182:1 anybody, including you, "Tell me about the tilt	
	182:2 resistance of your product," was your instruction	
	182:3 to play that down?	
	182:4 A. No.	
	182:5 Q. Okay. What was your instruction?	
	182:6 A. I don't remember what my instruction would	
	182:7 have been.	
184:2 - 184:17	**Hudnall, Janet 11-01-2013 (00:00:29)**	05_16_18 Combo Jones V3.57
	184:2 You're	
	184:3 saying to Dave, that, in fact, physicians will	HUNDNALL 24RAUCH.1.6
	184:4 often find that it's tilted quite a bit when they	
	184:5 go to retrieve it, even though it seemed perfectly	
	184:6 centered upon deployment, right?	
	184:7 A. Okay.	
	184:8 Q. How did you know that?	
	184:9 A. I guess we -- I guess people were calling	
	184:10 and saying that that's what they saw when they went	
	184:11 in to retrieve it.	
	184:12 Q. And "quite a bit" means what to you?	clear
	184:13 A. "Quite a bit" is -- I don't know. At the	

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	184:14 time --	
	184:15 Q. More than you expected?	
	184:16 (Speaking simultaneously.)	
	184:17 THE WITNESS: Yeah, sure.	
185:10 - 185:24	**Hudnall, Janet 11-01-2013 (00:00:41)**	05_16_18 Combo Jones V3.58
	185:10 Q. The question is: What did you mean when	
	185:11 you said that if you sell the device solely on this	
	185:12 feature, it could set the sales rep up for some	
	185:13 uncomfortable situations in the long run?	
	185:14 A. Oh, sure. Okay. Okay. So we have had	
	185:15 some people say that when they go in to retrieve	
	185:16 it, it looks tilted. So if -- apparently, Dave	
	185:17 created this document that talks all about how it	
	185:18 stays centered or it is centered, whatever it was,	
	185:19 and it was full of opinions, it sounds like. Okay?	
	185:20 So if a sales rep were to go in and sell based on	
	185:21 that approach, then he's going to have the hard	
	185:22 time passing the red-face test later on when the	
	185:23 physician goes in to retrieve it and it looks	
	185:24 tilted, because he's made these promises.	
186:18 - 187:2	**Hudnall, Janet 11-01-2013 (00:00:29)**	05_16_18 Combo Jones V3.59
	186:18 Q. If, in fact, you had an unexpected number	
	186:19 of tilting of this device, even after properly was	
	186:20 deployed and centering, and you knew that tilting	
	186:21 led to other evils with respect to the device,	
	186:22 including migration, perforation, and fracture,	
	186:23 isn't that something that doctors ought to know?	
	186:24 A. I did not know that at the time.	
	186:25 Q. But isn't that something that doctors	
	187:1 ought to know?	
	187:2 A. Sure, sure.	
187:10 - 187:14	**Hudnall, Janet 11-01-2013 (00:00:08)**	05_16_18 Combo Jones V3.60
	187:10 Q. BY MR. LOPEZ: No one told you that? No	
	187:11 one told you that tilting --	
	187:12 A. I don't have to be told things to know,	
	187:13 first of all, but no, we never concluded that it	
	187:14 leads to these evils.	
273:3 - 274:4	**Hudnall, Janet 11-01-2013 (00:01:03)**	05_16_18 Combo Jones V3.62 HUDNALL29.3.1
	273:3 Q. And there's a question here, "What is the	
	273:4 migration rate for Recovery?"	

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	273:5 A. Okay. 273:6 Q. Was that a question? Why is that question 273:7 there? Because you anticipate those line of 273:8 questions from the marketplace? 273:9 A. Probably.	
	273:10 Q. And your answer was, "It is very difficult 273:11 to determine actual rates because it is impossible 273:12 to know the exact number of filters implanted, not 273:13 only for Recovery, but for all commercially 273:14 available filters," right? 273:15 A. That's true.	HUDNALL29.3.2
	273:16 Q. "The only way to come close to comparing 273:17 apples to apples is to review the number of 273:18 reported incidents to the FDA MAUDE database," 273:19 right? 273:20 A. Okay. 273:21 Q. I asked you earlier about this. You're 273:22 saying here that the only thing that the world has 273:23 available to get any idea about how devices compare 273:24 to each other from the standpoint of risk and 273:25 complications is the MAUDE database? 274:1 A. Okay. 274:2 Q. Okay. That's what you're saying in this 274:3 memo, best you got, right? 274:4 A. I guess so.	HUDNALL29.3.3
296:9 - 296:19	**Hudnall, Janet 11-01-2013 (00:00:25)** 296:9 Let's look at the next one: "Is Recovery 296:10 a safe device?" And you told them to answer it 296:11 this way: "The Recovery filter was rigorously 296:12 tested for all physical performance -- performance 296:13 characteristics according to our established tested 296:14 methods and protocols. For all performance 296:15 criteria, the Recovery performed as well as or 296:16 better than the Simon Nitinol filter, the predicate 296:17 device." 296:18 That's what you wanted them to tell 296:19 people, right?	05_16_18 Combo Jones V3.63 HUDNALL29.4.1
296:21 - 297:7	**Hudnall, Janet 11-01-2013 (00:00:22)** 296:21 THE WITNESS: That was the truth. 296:22 Q. BY MR. LOPEZ: Okay. Now, "As for	05_16_18 Combo Jones V3.64 HUDNALL29.4.3

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	296:23 migration resistance, we first determined the 296:24 pressure graded," and you went on to talk about 296:25 what you did to determine migration resistance, 297:1 correct? 297:2 A. Uh-huh. 297:3 Q. Is that right? 297:4 A. Yes. 297:5 Q. So you wanted the world to believe that 297:6 the Simon Nitinol -- the Recovery filter actually 297:7 performed better than the Simon Nitinol filter?	HUDNALL29.4
297:9 - 297:18	**Hudnall, Janet 11-01-2013 (00:00:23)** 297:9 Q. BY MR. LOPEZ: Effectiveness and safety? 297:10 A. I wanted the world to know exactly what it 297:11 says here. 297:12 Q. Okay. But isn't the takeaway message from 297:13 whatever is said there to the listener, this 297:14 product is outperforming the Simon Nitinol filter 297:15 from a safety and efficacy standpoint? You don't 297:16 think that's -- 297:17 A. The takeaway message is exactly what's 297:18 written.	05_16_18 Combo Jones V3.65 clear
297:19 - 298:11	**Hudnall, Janet 11-01-2013 (00:00:38)** 297:19 Q. Well, I am asking you as a marketer when 297:20 you say that these things, that the Recovery 297:21 performed as well or better than the Simon Nitinol 297:22 filter, aren't you telling the world that the 297:23 Recovery filter is safer and more effective than 297:24 the Simon Nitinol filter? 297:25 A. No. 298:1 Q. You don't think so? 298:2 A. No. I wrote it. 298:3 Q. I know, but this is meant -- 298:4 A. This is at face value. Take this at face 298:5 value. 298:6 Q. I am not going to take it at face value. 298:7 I am asking you as a marketer, isn't your message: 298:8 Our Recovery filter is safer and more effective 298:9 than the Simon Nitinol filter? 298:10 A. I was asking the reader to take this at 298:11 face value.	05_16_18 Combo Jones V3.66 HUDNALL29.4.4

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316:9 - 316:16	**Hudnall, Janet 11-01-2013 (00:00:24)** 316:9 Q. If you look at it compared to the Simon 316:10 Nitinol filter, at least from a percentage-basis, 316:11 there's almost a 20 -- what is that -- almost a 316:12 2500 percent increase in migrations between the 316:13 Recovery and the Simon Nitinol filter? 316:14 A. Okay. 316:15 Q. Do you agree with me? 316:16 A. I agree with you on that.	05_16_18 Combo Jones V3.67 clear
316:19 - 317:9	**Hudnall, Janet 11-01-2013 (00:00:28)** 316:19 Q. BY MR. LOPEZ: Do you think that's 316:20 equivalent? 316:21 A. I have to go back to risk/benefit. 316:22 Q. I am asking you from just a pure 316:23 standpoint of that being -- 316:24 A. Just looking at numbers, no, it is not 316:25 comparable. 317:1 Q. Just looking at it from pure safety 317:2 standpoint? 317:3 A. Looking at purely these numbers, no. 317:4 Q. From a pure safety standpoint? 317:5 A. Looking at a pure numbers standpoint, it 317:6 looks like they are not comparable. 317:7 Q. It looks like the Recovery from a 317:8 migration standpoint is more dangerous than the 317:9 Simon Nitinol filter?	05_16_18 Combo Jones V3.68
317:11 - 317:13	**Hudnall, Janet 11-01-2013 (00:00:05)** 317:11 THE WITNESS: Looking at these numbers, 317:12 purely at these numbers, I am not going to make 317:13 judgment, they are not comparable.	05_16_18 Combo Jones V3.69
358:5 - 358:15	**Hudnall, Janet 11-01-2013 (00:00:34)** 358:5 Q. You were asked at some 358:6 point in time to deal with another FAQ regarding 358:7 the G2 filter, and one of the questions was what 358:8 other databases are out there to track medical 358:9 device-related injuries, and you recall that your 358:10 answer was unfortunately MAUDE is the only source 358:11 of this type of information? 358:12 A. Yes. 358:13 Q. It was the best information the company	05_16_18 Combo Jones V3.70

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	358:14 had?	
	358:15 A. It's the only information.	
359:9 - 359:13	**Hudnall, Janet 11-01-2013 (00:00:25)**	05_16_18 Combo Jones V3.71
	359:9 Q. And the number of migrations significantly	
	359:10 different, not comparable, not the same, .13	
	359:11 percent migration versus the Simon Nitinol filter,	
	359:12 I don't know, what's that about 15,000 percent	
	359:13 different?	
359:16 - 360:8	**Hudnall, Janet 11-01-2013 (00:00:43)**	05_16_18 Combo Jones V3.72
	359:16 Q. BY MR. LOPEZ: Isn't that just a dramatic	
	359:17 difference when you compare the Recovery to the	
	359:18 Simon Nitinol filter?	
	359:19	
	359:20 Q. BY MR. LOPEZ: When it comes to migration?	
	359:21 A. Based on that information, yes.	
	359:22 Q. This is based on information from actual	
	359:23 data that the company had?	
	359:24 A. Based on actual data the company had, yes.	
	359:25 Q. And filter embolization, that means the	
	360:1 filter is going somewhere distant to another part	
	360:2 of the body, right?	
	360:3 A. Okay.	
	360:4 Q. Look at the difference between the	
	360:5 Recovery filter and the Simon Nitinol filter for	
	360:6 embolizations.	
	360:7 A. Is there a question there?	
	360:8 Q. Isn't that a dramatic difference?	
360:10 - 360:12	**Hudnall, Janet 11-01-2013 (00:00:05)**	05_16_18 Combo Jones V3.73
	360:10 THE WITNESS: Yes.	
	360:11 Q. BY MR. LOPEZ: That's like 4,000 percent	
	360:12 difference?	
360:14 - 360:14	**Hudnall, Janet 11-01-2013 (00:00:00)**	05_16_18 Combo Jones V3.74
	360:14 THE WITNESS: Okay.	
361:8 - 361:11	**Hudnall, Janet 11-01-2013 (00:00:10)**	05_16_18 Combo Jones V3.75
	361:8 The	
	361:9 differences in these significant complications that	
	361:10 could lead to death are dramatic?	
	361:11 A. Okay.	
361:13 - 361:13	**Hudnall, Janet 11-01-2013 (00:00:00)**	05_16_18 Combo Jones V3.76
	361:13 Q. BY MR. LOPEZ: Would you agree with me,	

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361:17 - 361:22	**Hudnall, Janet 11-01-2013 (00:00:10)** 361:17 THE WITNESS: They are higher, yes. 361:18 Q. BY MR. LOPEZ: If you had to choose 361:19 between "comparable" or "dramatic," which word 361:20 would you use? 361:21 A. I wouldn't use either. I would say it is 361:22 higher.	05_16_18 Combo Jones V3.77
380:3 - 380:7	**Hudnall, Janet 11-01-2013 (00:00:12)** 380:3 Q. Well, but we knew -- we 380:4 know that there was -- with respect to the G2 was 380:5 being designed to have a greater adherence and 380:6 attachment to the cava wall? 380:7 A. And still allow retrievability, yes.	05_16_18 Combo Jones V3.78
380:11 - 380:16	**Hudnall, Janet 11-01-2013 (00:00:09)** 380:11 Q. But to still allow retrievability 380:12 but still have the same protection against 380:13 migration that a permanent device would have? 380:14 A. Yes, yes. 380:15 Q. And the reason that this thing was 380:16 migrating	05_16_18 Combo Jones V3.79
380:16 - 380:20	**Hudnall, Janet 11-01-2013 (00:00:13)** 380:16 is because the 380:17 Recovery did, in fact, quote, have a weak 380:18 attachment, end quote, that didn't allow it to stop 380:19 thrombi from dislodging it and sending it to the 380:20 heart, true?	05_16_18 Combo Jones V3.84 HUDNALL 34 236_BPV.1.5 clear
380:22 - 380:23	**Hudnall, Janet 11-01-2013 (00:00:04)** 380:22 THE WITNESS: Very, very simplified, yeah, 380:23 I guess it is true. I don't know.	05_16_18 Combo Jones V3.80

Plaintiffs Designations = 00:23:58
DefenseDesignations = 00:03:49
P & D Designations = 00:00:23
Total Time = 00:28:10

Documents Shown
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HUDNALL23
HUDNALL29
HUNDNALL 24RAUCH

Exhibit H

Designation Run Report

Little_COMBO_0522_R09

Little, William 07-27-2016

PL 00:05:32

DEF 00:15:46

Both 00:01:00

Total Time 00:22:18

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10:7 - 10:9	**Little, William 07-27-2016 (00:00:07)** 10:7 Q. All right. It's my understanding that you have 10:8 been in the medical device industry since April 10:9 of 2001?	Little_COMBO_0522_R09.1
10:12 - 10:12	**Little, William 07-27-2016 (00:00:04)** 10:12 A. I started long before that, approximately 1995.	Little_COMBO_0522_R09.2
20:21 - 20:22	**Little, William 07-27-2016 (00:00:03)** 20:21 Q. Tell us quickly from your perspective what an 20:22 IVC filter is.	Little_COMBO_0522_R09.3
21:11 - 21:14	**Little, William 07-27-2016 (00:00:08)** 21:11 So these devices are designed to be put in 21:12 place to prevent those blood clots from 21:13 ultimately causing tremendous harm to these 21:14 patients.	Little_COMBO_0522_R09.4
48:10 - 49:8	**Little, William 07-27-2016 (00:00:51)** 48:10 Q. If there was a fracture of the filter that 48:11 traveled to the heart and perforated through her 48:12 heart, that would be a significant clinical 48:13 event? 48:14 A. Did -- was she injured by it? Did she -- I just 48:15 don't remember the outcome. 48:16 Q. You don't recall that she required emergency 48:17 open-heart surgery to correct the problem? 48:18 A. I don't, but I'll take your word for it. 48:19 Q. Okay. 48:20 A. And that would be a significant event. 48:21 Q. Okay. 48:22 A. If somebody had to undergo emergency open-heart 48:23 surgery, yeah, that's a significant adverse 48:24 event. And those things happen. And, again, 48:25 they're bad when they happen. 49:1 So yes, I would certainly characterize if 49:2 somebody had to have emergent surgery as a 49:3 significant adverse event, and so would the FDA. 49:4 Q. And I think you commented a little while ago 49:5 that filters -- these filters are not supposed 49:6 to break apart? 49:7 A. Right. That's not what they're designed to do, 49:8 no.	Little_COMBO_0522_R09.5
55:9 - 56:9	**Little, William 07-27-2016 (00:01:12)**	Little_COMBO_0522_R09.6

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55:9 Q. With respect to IVC filters and
55:10 during the three years that you were with Bard,
55:11 would you agree that it was absolutely mandatory
55:12 that Bard be transparent in their dealings with
55:13 doctors and provide not only good information
55:14 about their IVC filter line but also the bad
55:15 information?
55:16 A. Yeah. So when you start saying absolutely
55:17 mandatory, what our clinicians want is
55:18 actionable information that's appropriate.
55:19 So we tried to avoid information overload;
55:20 but generally, yeah, we're trying to give them
55:21 appropriate balanced information about the risks
55:22 and benefits of our devices in an appropriate
55:23 context so that they can make informed decisions
55:24 about their patients.
55:25 So I'm careful about absolute statements
56:1 because, you know, generally those tend to
56:2 overstate, but generally, yeah, we're trying to
56:3 provide fair and balanced information about
56:4 risks and benefits of our devices and that goes
56:5 back to FDA guidance.
56:6 Q. Setting aside FDA guidelines, do you understand
56:7 that to be an obligation of Bard; that is, to
56:8 provide good and bad information about its IVC
56:9 filter line in its dealings with doctors?

56:13 - 56:18 **Little, William 07-27-2016 (00:00:16)** Little_COMBO_0522_R09.7

56:13 communication, the -- you know, the instructions
56:14 for use. It's also, you know, as marketing guy,
56:15 we had our own internal policies that talked
56:16 about, you know, fair balance, and that we have
56:17 appropriate backup for whatever claims, you
56:18 know, we would make.

57:4 - 57:25 **Little, William 07-27-2016 (00:00:59)** Little_COMBO_0522_R09.8

57:4 Q. Why is it important to give a doctor not only
57:5 the good information about an IVC filter, but
57:6 also the bad information?
57:7 A. Well, I think it's important that you provide
57:8 appropriate balance in what we give clinicians.
57:9 And with any device, there are risks and

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	57:10 benefits. 57:11 It's important because, A, the FDA mandates 57:12 it and, B, it's the right thing to do. 57:13 And giving clinicians appropriate 57:14 information about risks and benefits of devices 57:15 helps them take better care of patients and 57:16 ultimately helps us sell more stuff. 57:17 If we over the long-run provide good 57:18 information and we are trustworthy, that helps 57:19 the long-term growth of the company. And if we 57:20 take something shortsighted or unbalanced, you 57:21 know, that short little peak that you may have 57:22 ultimately comes back to -- to harm the overall 57:23 company. 57:24 So it's doing the right thing over time was 57:25 kind of what we tried to do.	
64:16 - 65:1	**Little, William 07-27-2016 (00:00:29)** 64:16 Q. Do you agree that a company like Bard should not 64:17 put profits for the sales of its IVC filters 64:18 over patient safety? 64:19 A. I do agree with that. 64:20 Q. All right. 64:21 A. Patient safety is paramount to what we do and 64:22 they go hand in hand. And if you make devices 64:23 that aren't safe, profits ultimately go away. 64:24 And the way for us to be successful was to focus 64:25 on continuous improvement, put the patient 65:1 first. And we really did that.	Little_COMBO_0522_R09.9
144:13 - 145:8	**Little, William 07-27-2016 (00:00:52)** 144:13 Q. All right. As part of your work at Bard -- 144:14 A. Mm-hmm (affirmative). 144:15 Q. -- did you gain a general understanding of how 144:16 the vena cava works; that is, the dynamics of 144:17 the vena cava? 144:18 A. Generally. I mean, I know that they're 144:19 pulsatile, that they're dynamic, that they 144:20 stretch and move. And I learn generally by 144:21 reading the occasional clinical article or 144:22 hearing from clinicians or even from our own 144:23 bench testing. So I would say generally, yes,	Little_COMBO_0522_R09.10

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	144:24 but I wouldn't consider myself an expert. 144:25 Q. And what bench testing data do you recall 145:1 reviewing that addressed the issue of vena caval 145:2 dynamics? 145:3 A. I recall that we had seen maybe some imaging 145:4 testing where we saw how the vena cava is 145:5 dynamic and that it moved. I couldn't point you 145:6 specifically to what that was, but I do remember 145:7 that. It's five or six years ago, but I 145:8 remember something about that.	
145:9 - 145:25	**Little, William 07-27-2016 (00:00:40)** 145:9 Q. Was that something that was learned, I guess, in 145:10 2008 after you joined Bard? 145:11 A. I don't know if it was -- I learned it after 145:12 2008. I don't know when we learned it. I 145:13 suspect we did. But I don't know for sure when 145:14 that was originally learned. 145:15 Q. Do you have a firsthand understanding of how 145:16 Bard accounted for vena caval dynamics in its 145:17 bench testing? 145:18 A. I don't. 145:19 Q. You would agree, though, it would be important 145:20 to account for vena caval dynamics in bench 145:21 testing? 145:22 A. Yeah. I think that if we were aware of 145:23 something about dynamics, then that would be a 145:24 design input that could be important to 145:25 designing a filter.	Little_COMBO_0522_R09.11
146:1 - 146:14	**Little, William 07-27-2016 (00:00:35)** 146:1 Q. Well, when designing a filter, doesn't it make, 146:2 you know, common sense that you have to have an 146:3 understanding of your environment of use when 146:4 designing and conducting bench testing on a 146:5 medical device like an IVC filter? 146:6 A. So you do the best you can, right? We have 146:7 incomplete information. The more we can get 146:8 the, better. And, you know, a lot of this as 146:9 we're going, we're learning alongside our 146:10 clinicians and the FDA. 146:11 So, yes, it's important that we know what	Little_COMBO_0522_R09.12

Page/Line	Source	ID
	146:12 we can know but with the limitation that we 146:13 can't know everything and it's a continuous 146:14 improvement-type process.	
157:5 - 157:8	**Little, William 07-27-2016 (00:00:14)** 157:5 Q. All right. Go ahead and review that document 157:6 and tell me whether it identifies warnings or 157:7 concerns or references, filter tilt, filter 157:8 migration, or filter fracture?	Little_COMBO_0522_R09.13
157:10 - 157:10	**Little, William 07-27-2016 (00:00:02)** 157:10 I don't see any of that in here.	Little_COMBO_0522_R09.14
160:6 - 160:13	**Little, William 07-27-2016 (00:00:18)** 160:6 Q. All right. 160:7 A. We would need broader information. Certainly a 160:8 clinician, you know, as part of their 160:9 discussions with patients would absolutely be 160:10 required to discuss the risks and benefits of 160:11 any procedure. And this is one important part, 160:12 but this is not in isolation the complete story 160:13 for a patient.	Little_COMBO_0522_R09.16
160:18 - 161:2	**Little, William 07-27-2016 (00:00:30)** 160:18 Q. My question is: Looking at this language in the 160:19 document prepared by Bard to be provided to a 160:20 patient, it does not tell the complete truth 160:21 with respect to removability of the G2 filter? 160:22 A. I wouldn't say that. I wouldn't say that it 160:23 doesn't tell the complete truth. I mean, 160:24 certainly, devices can be removed. You can 160:25 remove them one way or another, whether it is 161:1 through retrieval cone, through surgical option, 161:2 through a snare.	Little_COMBO_0522_R09.17
167:22 - 168:5	**Little, William 07-27-2016 (00:00:21)** 167:22 Q. And these documents are given to patients so 167:23 that they can read them and they can then be 167:24 prepared to ask questions, correct? 167:25 A. Certainly they're given to the patients for a 168:1 lot of reasons. And then their discussion with 168:2 the clinician is part of it. And we always talk 168:3 about clinicians having discussions with 168:4 patients about risks and benefits of both 168:5 implant or any procedure that they go under.	Little_COMBO_0522_R09.18

Page/Line	Source	ID
170:8 - 170:13	**Little, William 07-27-2016 (00:00:12)** 170:8 They should get discussions with 170:9 clinicians, and they should have access to 170:10 additional information beyond this. 170:11 Hopefully, this is helpful. But this would 170:12 not be the lone piece of information a patient 170:13 should get.	Little_COMBO_0522_R09.19
187:3 - 187:7	**Little, William 07-27-2016 (00:00:22)** 187:3 Q. All right. The next exhibit, this is the 187:4 document that appears to have been sent to you 187:5 from Filter Marketing. It's dated April 27, 187:6 2010. Do you see that? 187:7 A. Yeah.	Little_COMBO_0522_R09.20
187:18 - 187:24	**Little, William 07-27-2016 (00:00:17)** 187:18 Q. Eclipse Anchors, do you have a recollection of 187:19 what those were? 187:20 A. So Eclipse was a product line. And then 187:21 Anchors, you know, this was probably a project 187:22 name of the Eclipse filter that we were going to 187:23 put anchors on. And it looks like a naming 187:24 document of, How should we brand this.	Little_COMBO_0522_R09.21
187:25 - 188:11	**Little, William 07-27-2016 (00:00:29)** 187:25 Q. And what we know is that as of April 27, 2010, 188:1 Bard had this concept of Eclipse Anchors; 188:2 correct? 188:3 A. Again, I don't recall this document, so I don't 188:4 know. 188:5 Q. All right. 188:6 A. Oh, "proposed named, Denali." Okay. So that 188:7 became Denali. 188:8 Now it's tracking when I see on page 2, I 188:9 see Denali, which, we did have a project that we 188:10 ultimately called Denali. So that makes more 188:11 sense now.	Little_COMBO_0522_R09.22
188:12 - 188:15	**Little, William 07-27-2016 (00:00:09)** 188:12 Q. But the concept, the technology of Eclipse 188:13 Anchors, is being discussed as of April 27, 188:14 2010? 188:15 A. Yes.	Little_COMBO_0522_R09.23
188:16 - 188:25	**Little, William 07-27-2016 (00:00:26)**	Little_COMBO_0522_R09.24

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	188:16 Q. And there's a heading in this 188:17 document titled "Value Proposition." What is a 188:18 "value proposition"? 188:19 A. So a value proposition is how we describe the 188:20 essential benefits of a device to a given 188:21 audience. And it can vary, so you can have a 188:22 value proposition for a patient, for a 188:23 clinician, for a payer, for a nurse. The value 188:24 propositions can vary. But it is, you know, 188:25 what is it that's valuable about this.	
189:1 - 189:6	**Little, William 07-27-2016 (00:00:15)** 189:1 Q. And this first sentence states "The Eclipse 189:2 Anchor filter will retain the advantages of G2, 189:3 G2X, Eclipse, including the retrievable 189:4 indication while improving caudal migration 189:5 resistance." 189:6 A. Yep.	Little_COMBO_0522_R09.25
189:7 - 189:20	**Little, William 07-27-2016 (00:00:30)** 189:7 Q. What was the problem with caudal migration 189:8 resistance that related to the G2, G2X, and 189:9 Eclipse? 189:10 A. Well, I don't know that I would describe it as a 189:11 problem, but the device -- what you're trying to 189:12 improve upon is any movement, right? And in the 189:13 spirit of continuous improvement we just showed 189:14 in the previous document, that, at least in the 189:15 EVEREST study, there was some caudal migration 189:16 of filters moving down. 189:17 So in the spirit of, Okay, let's try to 189:18 make that better, well, then, you make design 189:19 improvements that would reduce the likelihood of 189:20 that happening. So that's how I take it.	Little_COMBO_0522_R09.26
189:21 - 190:11	**Little, William 07-27-2016 (00:00:39)** 189:21 Q. Well, referring back to Exhibit 2002, which was 189:22 the G2 filter brochure -- 189:23 A. Yeah. 189:24 Q. -- it discusses increased migration resistance. 189:25 A. Yep. 190:1 Q. All right. So there appears to be a problem 190:2 with the G2 filter based on this document?	Little_COMBO_0522_R09.27

Page/Line	Source	ID
	190:3 A. So things can migrate two different ways. You 190:4 can migrate cranial towards the head or caudally 190:5 towards the feet. So as I recall, caudal 190:6 migration was fairly new, and we hadn't seen a 190:7 lot of that. And I think that's what drove the 190:8 desire for, okay, let's improve caudal 190:9 migration, too. 190:10 That's how I recall this. But, again, it's 190:11 been a little while.	
190:12 - 191:6	**Little, William 07-27-2016 (00:00:41)** 190:12 Q. Well, if G2 was first cleared in 2005, we're now 190:13 in 2010, why is it taking so long to correct 190:14 this migration issue? 190:15 A. Well, I don't know that "correcting" is the 190:16 right term. And it takes a long time to develop 190:17 medical devices. There's R&D work. There's 190:18 bench work. There's design work. 190:19 And nothing happens overnight. We all wish 190:20 it would happen faster, but iterations take time 190:21 to improve devices. It just takes a while. 190:22 MR. LOPEZ: I think the question 190:23 was why five years. 190:24 THE WITNESS: Yeah. I don't know. 190:25 I don't know. But that doesn't seem that 191:1 unusual to me. I mean, typically, we'll 191:2 have five-year product life cycle cadences 191:3 where you'll look and say, Here's our 191:4 pipeline of products. 191:5 Or, like, when we do a strategic 191:6 plan, it's typically a five-year plan.	Little_COMBO_0522_R09.28
194:7 - 194:14	**Little, William 07-27-2016 (00:00:15)** 194:7 Q. All right. And so you're referring to Exhibit 194:8 2004 would be potentially a source of 194:9 information that a sales representative could 194:10 give the medical community about caudal 194:11 migration? 194:12 A. I don't know that it was approved for 194:13 internal-external use. You'd have to be careful 194:14 with that so --	Little_COMBO_0522_R09.29
200:5 - 200:10	**Little, William 07-27-2016 (00:00:10)**	Little_COMBO_0522_R09.31

Page/Line	Source	ID
	200:5 Q. All right. 200:6 How is it that improving caudal migration 200:7 resistance should reduce tilt, fracture, 200:8 and penetration? 200:9 A. That's why I'm not sure I believe it. I'm not 200:10 sure that it does.	
200:17 - 200:23	**Little, William 07-27-2016 (00:00:20)** 200:17 Q. Have you learned or did you become aware that 200:18 when a filter caudally migrates, it tends to 200:19 tilt; that, in turn, leads to fracture -- I'm 200:20 sorry -- that, in turn, leads to penetration; 200:21 which can, in turn, lead to fracture? 200:22 A. I don't doubt that that's true. But I'm not 200:23 expert enough to know that.	Little_COMBO_0522_R09.32
200:24 - 201:4	**Little, William 07-27-2016 (00:00:15)** 200:24 Q. All right. But, obviously, somebody was 200:25 concerned about caudal migration as it relates 201:1 to tilt, fracture, and penetration? 201:2 A. Yeah. And this was likely written by a 201:3 marketing team member, not necessarily one of 201:4 the clinicians or R&D guys.	Little_COMBO_0522_R09.33
202:11 - 203:7	**Little, William 07-27-2016 (00:00:50)** 202:11 Q. What is it about improved stability that is 202:12 being referenced here? 202:13 A. Yeah. I mean, to oversimplify it, so if you're 202:14 a clinician and I went to you and said, Okay, 202:15 Doctor, do you want the filter that's stable or 202:16 the filter that's unstable? Generally, they 202:17 would say, Well, if everything else were equal, 202:18 I'll take the one that's stable. 202:19 And that oversimplifies it, but yeah. 202:20 Q. Well, let me oversimplify it as well. 202:21 A. Yeah. 202:22 Q. We can agree that stability of the filter is the 202:23 foundation for a safe and effective filter? 202:24 A. Oh, I'm not sure of that, no. I disagree. 202:25 The foundation of "effective" is how well 203:1 does it block clot. That is the foundation. 203:2 Q. All right. Tell me where my disconnect is. 203:3 A. So if you had a filter that didn't move at all	Little_COMBO_0522_R09.35

Page/Line	Source	ID
	203:4 and didn't block a clot at all, that would be 203:5 bad. 203:6 And if you had one that moved a little bit 203:7 but blocked all the clots, that would be better.	
205:3 - 205:15	**Little, William 07-27-2016 (00:00:36)** 205:3 Q. And as of April of 2010, what baggage existed 205:4 with the G2, the G2X, and the Eclipse filters? 205:5 A. Well, so a lot of this was probably related to 205:6 the filter law website. Look, that was a lot of 205:7 baggage we had to deal with. It was really hard 205:8 for us to deal with. 205:9 We had that. We also had competitors 205:10 pointing at the MAUDE database, which by its 205:11 very nature you can't use it to compare rates. 205:12 But that's what they were doing, and the 205:13 realty is we had to deal with that. And if you 205:14 want to call that "baggage," that was baggage. 205:15 We had to deal with.	Little_COMBO_0522_R09.36 clear
207:25 - 208:14	**Little, William 07-27-2016 (00:00:37)** 207:25 Q. And you understand that the reason for 208:1 electropolishing was to improve the fracture 208:2 resistance of the filters? 208:3 A. We thought that. We thought that it would 208:4 reduce surface imperfections, which could 208:5 potentially lead to fractures. And I don't know 208:6 that that ever played out that way. But at the 208:7 time that was the thinking. 208:8 Q. All right. Do you know what the results were 208:9 with respect to electropolishing as of the time 208:10 you left Bard? 208:11 A. I don't. I don't know. I don't recall. 208:12 Q. All right. 208:13 A. We electropolished it, but I don't know if that 208:14 translated into changes in fracture rates.	Little_COMBO_0522_R09.38
208:16 - 208:24	**Little, William 07-27-2016 (00:00:19)** 208:16 Q. The next sentence: "The change in brand name 208:17 and codes was to create a break with the baggage 208:18 associated with the previous versions despite 208:19 the fact that the new iteration was the same as 208:20 G2X in every way but one."	Little_COMBO_0522_R09.39

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	208:21 Did I read that correctly?	
	208:22 A. Mm-hmm (affirmative).	
	208:23 Q. Yes?	
	208:24 A. Yes.	
208:25 - 209:2	**Little, William 07-27-2016 (00:00:06)**	Little_COMBO_0522_R09.40
	208:25 Q. All right. And it doesn't tell us what the	
	209:1 baggage is that that is referring to, does it?	
	209:2 A. No.	
209:3 - 209:14	**Little, William 07-27-2016 (00:00:35)**	Little_COMBO_0522_R09.41
	209:3 Q. And what they're saying is, We're	
	209:4 going to change the name of this filter and	
	209:5 we're going to disassociate ourselves with the	
	209:6 baggage even though it's the same filter other	
	209:7 than the fact that it's been electropolished?	
	209:8 A. Well, and as we talked about before, that	
	209:9 baggage, I think a lot of that was unjust,	
	209:10 unfair baggage. I mean, if we looked at what	
	209:11 came with filter law and what came with our	
	209:12 competitors out there, so having something that	
	209:13 could potentially improve upon any kind of	
	209:14 fracture rates is a good thing.	
210:4 - 210:6	**Little, William 07-27-2016 (00:00:06)**	Little_COMBO_0522_R09.42
	210:4 Q. Yeah. And baggage can be the perception of this	
	210:5 filter in the eyes of doctors, correct?	
	210:6 A. Yeah, it could have been.	
229:18 - 229:19	**Little, William 07-27-2016 (00:00:05)**	Little_COMBO_0522_R09.43
	229:18 Q. All right. So she's identifying that as an	
	229:19 enemy of Bard?	
229:22 - 230:10	**Little, William 07-27-2016 (00:00:27)**	Little_COMBO_0522_R09.44
	229:22 We could talk about this all day. I mean,	
	229:23 this to me is -- this is -- so reinforces the	
	229:24 culture of we've got this cross-functional team	
	229:25 that's out here taking an honest assessment of	
	230:1 ourselves, saying, "Hey, we have to make sure we	
	230:2 don't have processes that get in the way. We've	
	230:3 got to build robust products. We have to	
	230:4 develop evidence. We have to do all these right	
	230:5 things.	
	230:6 There is a culture of do the right thing	
	230:7 here. And this is a pretty good document that	

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	230:8 says that. And, you know, what's so 230:9 interesting, when I look at the bottom one, 230:10 which isn't highlighted --	
359:1 - 359:2	**Little, William 07-27-2016 (00:00:04)** 359:1 Q. Take a look at Exhibit 2009. 359:2 A. Okay.	Little_COMBO_0522_R09.45
359:20 - 360:9	**Little, William 07-27-2016 (00:00:37)** 359:20 Q. And how is it that you, as vice president of 359:21 global marketing, would have been tasked with 359:22 the preparation of this document? 359:23 A. So it looks like this is a communication 359:24 document, and part of our role in marketing is 359:25 to work on communication. I mean, we talk about 360:1 talking points; what are we going to say? 360:2 People are going to ask us and say, "Okay, what 360:3 do you know about this?" 360:4 And what we try to do is get them the facts 360:5 and, you know, stick to what we know to be true. 360:6 And so we write that down, and we vet it and 360:7 make sure that it's accurate because, you know, 360:8 this stuff's important. So when I told you we 360:9 saw the video, this was something we acted on.	Little_COMBO_0522_R09.46
390:14 - 390:14	**Little, William 07-27-2016 (00:00:01)** 390:14 Q. What are the SIR guidelines?	Little_COMBO_0522_R09.47
390:19 - 391:11	**Little, William 07-27-2016 (00:00:35)** 390:19 A. The Society of Interventional Radiology is sort 390:20 of the guiding society for interventional 390:21 radiologists. 390:22 BY MR. LOPEZ: 390:23 Q. Right. 390:24 A. They issue guidelines which are how they think 390:25 they should -- that their members should treat 391:1 patients. And then with that, they frequently 391:2 will cite literature that would give clinicians 391:3 ranges in which they would expect outcomes to 391:4 be. 391:5 Q. Right. 391:6 A. Those outcomes could be clinical outcomes. They 391:7 could be complication rates. And then within 391:8 SIR guidelines, I believe there are guidelines	Little_COMBO_0522_R09.48

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	391:9 around filters. And then within filters, there 391:10 are ranges of what you should expect for things 391:11 like fracture or migration.	
392:1 - 392:10	**Little, William 07-27-2016 (00:00:22)** 392:1 Q. It's just a report of the historical nature of 392:2 some of the reports in the literature about a 392:3 variety of IVC filters. 392:4 A. No. That's not what guidelines are. Guidelines 392:5 are not a report about some of the literature 392:6 that are out there. That's wildly different. 392:7 When you're talking about guidelines from a 392:8 society, that is the highest level document that 392:9 they have. It's not just some amalgamation of 392:10 some data.	Little_COMBO_0522_R09.49
430:18 - 430:25	**Little, William 07-27-2016 (00:00:12)** 430:18 Q. Mr. Little, good afternoon. 430:19 A. Good afternoon. 430:20 Q. As you know, I am one of the attorneys 430:21 representing C.R. Bard and also here 430:22 representing you in your personal capacity 430:23 today, and my name is Jim Rogers, and I'm going 430:24 to ask you a few additional questions. 430:25 A. Okay.	Little_COMBO_0522_R09.50
441:5 - 441:24	**Little, William 07-27-2016 (00:00:56)** 441:5 Q. And is it important for a business like Bard 441:6 that is selling medical devices to have sound 441:7 relationships with doctors? 441:8 A. Yes. 441:9 Q. And is that something that is important from a 441:10 long-term perspective? 441:11 A. It's critical from a long-term perspective. 441:12 Q. Can you explain that? 441:13 A. Yeah. So, you know, Bard's a company that's 441:14 been around for over a hundred years, and we 441:15 think about the business over the long run. And 441:16 making sound decisions, good investments, being 441:17 thoughtful about how we communicate to patients, 441:18 to investors, to the FDA, all of that goes into 441:19 being a company that's successful over a 441:20 century. And we were serious about that.	Little_COMBO_0522_R09.51

Page/Line	Source	ID
	441:21 It wasn't about, you know, this quarter, 441:22 this sale, this product. It was about long term 441:23 doing the right thing and building the value of 441:24 the company, and I think we did that.	
442:10 - 442:13	**Little, William 07-27-2016 (00:00:11)** 442:10 Q. If there has been any suggestion during your 442:11 deposition or in this case that Bard made 442:12 decisions motivated by profits over patient 442:13 safety, how would you respond to that?	Little_COMBO_0522_R09.52
442:18 - 443:2	**Little, William 07-27-2016 (00:00:22)** 442:18 A. I would disagree, and I would say that that was 442:19 not what I saw when I was there. These were 442:20 good people working hard, trying to do the right 442:21 thing; trying to do, you know, continuous 442:22 improvements. When they saw potential adverse 442:23 events, they didn't run from them. In fact, 442:24 they went the other way. They highlighted them 442:25 and said, "Let's get after this. Let's fix 443:1 this." And that was the culture there when I 443:2 was there. That's what I saw.	Little_COMBO_0522_R09.53
463:8 - 463:24	**Little, William 07-27-2016 (00:00:43)** 463:8 Q. And describe generally what is Filter Facts. 463:9 A. So Filter Facts was a website that Bard 463:10 Peripheral Vascular put up where we could direct 463:11 any inquiries, whether it was patient, 463:12 physician, to a single site that was available 463:13 to all where they could get unbiased, balanced 463:14 information about risks and benefits. 463:15 We would put, you know, fair, balanced 463:16 clinical articles up there. We would put IFUs 463:17 up there. We had expert testimony up there so 463:18 that clinicians and patients could get a 463:19 different perspective other than the 463:20 fear mongering website that was up there. 463:21 It was intentionally designed to be fair 463:22 and balanced; not designed to be, you know, a 463:23 one-sided fear mongering website, which is what 463:24 we were dealing with.	Little_COMBO_0522_R09.54
482:16 - 482:17	**Little, William 07-27-2016 (00:00:03)** 482:16 Q. Well, with respect to the Warning section of	Little_COMBO_0522_R09.55

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	482:17 this IFU --	
482:19 - 482:20	**Little, William 07-27-2016 (00:00:05)**	Little_COMBO_0522_R09.56
	482:19 Q. -- would you agree with me that Bard cannot warn 482:20 away a device defect?	
483:19 - 484:5	**Little, William 07-27-2016 (00:00:26)**	Little_COMBO_0522_R09.57
	483:19 A. If you're suggesting that by putting it in a 483:20 warning that it doesn't happen, no, of course 483:21 that's not going to happen. But by putting it 483:22 in a warning in a section where clinicians are 483:23 taught to go look and to be aware, there's no 483:24 better place to put it. 483:25 So by labeling it there, it doesn't make it 484:1 go away. What it does is draw attention to it 484:2 and make sure that we fully disclose what's out 484:3 there so that clinicians and patients can 484:4 accurately understand risks and benefits of 484:5 procedures, and that is how we do it.	
485:6 - 485:9	**Little, William 07-27-2016 (00:00:08)**	Little_COMBO_0522_R09.58
	485:6 Q. And you raised an interesting point. You have 485:7 told us that you are the vice president of 485:8 global marketing. You are a marketing guy. 485:9 A. Yep.	
490:8 - 490:25	**Little, William 07-27-2016 (00:00:43)**	Little_COMBO_0522_R09.60
	490:8 Q. That was internal to Bard that they wanted to 490:9 get out to the public and to doctors, they could 490:10 have used a website like Filter Facts, right? 490:11 A. Could have, yes. 490:12 Q. For example, if Bard had statistically 490:13 significant data analysis that their device was 490:14 a lot more dangerous than other devices or even 490:15 a predicate device, they could have used Filter 490:16 Facts to let people know about that, right? 490:17 That Filter Facts -- 490:18 A. Could have. That's a website. You can put 490:19 anything -- what you want on a website. 490:20 Q. Anything you want? 490:21 A. Sure. 490:22 Q. No limitation? The FDA doesn't even have to 490:23 approve it? 490:24 A. I don't know about that. I don't think they	

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490:25 did, but I suspect that's true.

PL = 00:05:32
DEF = 00:15:46
Both = 00:01:00
Total Time = 00:22:18

Exhibit I

Designation Run Report

Moritz 07-18-17 Jones Trial Depo Designations V2

Moritz, Mark 07-18-2017

Plaintiffs Designations 00:08:24

Defense Designations 00:00:25

Total Time 00:08:49

Page/Line	Source	ID
6:8 - 6:13	**Moritz, Mark 07-18-2017 (00:00:07)** 6:8 Q. Doctor, would you state your 6:9 full name for the record, please. 6:10 A. Mark William Moritz. 6:11 Q. And, Dr. Moritz, you are a 6:12 vascular surgeon? 6:13 A. I am.	05_01_18 Jones Combo V2.1
43:11 - 43:19	**Moritz, Mark 07-18-2017 (00:00:19)** 43:11 Q. And do you agree that in 43:12 those interactions that a doctor must act 43:13 in the best interest of his patients? 43:14 A. I agree. 43:15 Q. And that means that a doctor 43:16 must rely on the medical device company 43:17 to give it complete, accurate and 43:18 thorough information about its devices, 43:19 fair?	05_01_18 Jones Combo V2.2
43:22 - 44:12	**Moritz, Mark 07-18-2017 (00:00:33)** 43:22 THE WITNESS: Yes. 43:23 BY MR. O'CONNOR: 43:24 Q. Okay. And among reasons 44:1 that's important is because as a medical 44:2 doctor and in treating your patients in 44:3 advising your plaintiffs -- your 44:4 patients, you need to be versed in risks 44:5 and benefits of a device, correct? 44:6 A. Correct. 44:7 Q. And when you engage in the 44:8 informed consent process, a patient 44:9 relies on you to not only advise him or 44:10 her of the risks or the benefits, but 44:11 also of the risks, correct? 44:12 A. Correct.	05_01_18 Jones Combo V2.3
101:5 - 101:10	**Moritz, Mark 07-18-2017 (00:00:18)** 101:5 Q. If you look at the last full 101:6 paragraph on Page 9, you've seen evidence 101:7 that Bard filters do fracture and that 101:8 those fractured pieces do embolize, 101:9 correct? 101:10 A. Correct.	05_01_18 Jones Combo V2.25

Page/Line	Source	ID
112:16 - 113:7	**Moritz, Mark 07-18-2017 (00:00:35)** 112:16 Q. Do you agree -- you talked 112:17 about it earlier. It seems as though 112:18 that over the years anticoagulation 112:19 therapy treatments have improved and have 112:20 become very effective? 112:21 A. Yes. 112:22 Q. And it sounds as though that 112:23 you're of the school of thought that if 112:24 anticoagulation is working, don't put a 113:1 filter in? 113:2 A. It depends on the 113:3 circumstance. 113:4 Q. But for sure you know from 113:5 the risk of failures that can occur, that 113:6 filters, Bard filters need to be removed 113:7 immediately after use?	05_01_18 Jones Combo V2.27
113:10 - 113:14	**Moritz, Mark 07-18-2017 (00:00:07)** 113:10 THE WITNESS: I don't agree 113:11 with the way that you put that. I 113:12 think all filters, not just Bard, 113:13 should be retrieved as soon as 113:14 they are no longer needed.	05_01_18 Jones Combo V2.28
113:21 - 114:4	**Moritz, Mark 07-18-2017 (00:00:16)** 113:21 Q. And I think one thing that 113:22 you have said, at least as it relates to 113:23 Bard filters and the work you've done in 113:24 this case, that you understand that for 114:1 these Bard retrievable filters, there's a 114:2 relationship between indwell time and the 114:3 risk of a complication? 114:4 A. Yes.	05_01_18 Jones Combo V2.29
122:2 - 122:6	**Moritz, Mark 07-18-2017 (00:00:10)** 122:2 Q. But one thing is for sure. 122:3 You would agree that the Bard filters 122:4 studied in Tam, Angel, and Nicholson were 122:5 not behaving as doctors would reasonably 122:6 expect permanent filters to behave?	05_01_18 Jones Combo V2.33
122:9 - 122:13	**Moritz, Mark 07-18-2017 (00:00:02)** 122:9 THE WITNESS: I would say	05_01_18 Jones Combo V2.34

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	122:10 so.	
	122:11 BY MR. O'CONNOR:	
	122:12 Q. You agree with me?	
	122:13 A. Yeah.	
122:14 - 124:1	**Moritz, Mark 07-18-2017 (00:01:24)**	05_01_18 Jones Combo V2.05
	122:14 Q. And then, is it -- how do	
	122:15 you say that? Vijay? Vijay?	
	122:16 A. We usually would say Vijay.	
	122:17 I think I know someone by that name.	
	122:18 MR. DEGREEFF: Vijay.	
	122:19 THE WITNESS: Yeah.	
	122:20 BY MR. O'CONNOR:	
	122:21 Q. It talks about risk of	
	122:22 fracture increase with indwell time of	
	122:23 the G2 -- the Recovery, G2, and G2X?	
	122:24 A. Yes.	
	123:1 Q. Correct?	
	123:2 A. Yes.	
	123:3 Q. And one thing that that	
	123:4 article mentioned is the concern about	
	123:5 embolization of fragments into the	
	123:6 pulmonary arteries?	
	123:7 A. Yes.	
	123:8 Q. And you agree that when a	
	123:9 fragment embolizes into the pulmonary	
	123:10 artery, that exposes a patient to a risk	
	123:11 of further complications?	
	123:12 A. It does.	
	123:13 Q. Which would include	
	123:14 bleeding, erosion, infection, vascular	
	123:15 thrombosis, true?	
	123:16 A. True.	
	123:17 Q. Or occlusion?	
	123:18 A. Probably not occlusion.	
	123:19 Q. And then is it An on Page	
	123:20 13? A-N?	
	123:21 A. Right.	
	123:22 Q. That article talked about	
	123:23 the G2 and how the risk of fracture	
	123:24 increased with indwell time.	

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	124:1 A. Yes.	
125:2 - 125:6	**Moritz, Mark 07-18-2017 (00:00:15)**	05_01_18 Jones Combo V2.31
	125:2 Q. and just above that, 125:3 Andreoli noted that fractures were more 125:4 commonly reported among Bard filters, 125:5 true? 125:6 A. True.	
129:10 - 129:16	**Moritz, Mark 07-18-2017 (00:00:17)**	05_01_18 Jones Combo V2.43
	129:10 Q. And that if Bard is aware 129:11 that its filters are experiencing 129:12 significant -- statistically significant 129:13 rates of complications, you as a 129:14 physician have a right to know that and 129:15 have a right to expect Bard to 129:16 communicate that to you?	
129:19 - 129:23	**Moritz, Mark 07-18-2017 (00:00:07)**	05_01_18 Jones Combo V2.41
	129:19 THE WITNESS: What I expect 129:20 is that Bard communicates with the 129:21 FDA, and together they confirm 129:22 that this is significant. And 129:23 then they notify me.	
135:23 - 136:19	**Moritz, Mark 07-18-2017 (00:00:42)**	05_01_18 Jones Combo V2.45
	135:23 Q. Where exactly in the 135:24 pulmonary artery? 136:1 A. The right side. 136:2 Q. And the pulmonary artery is, 136:3 I think you would agree, an important 136:4 vessel? 136:5 A. Yes. 136:6 Q. Why? 136:7 A. Well, the main pulmonary 136:8 artery on each side takes approximately 136:9 half the blood flow of the entire body 136:10 and delivers it to the lungs where it's 136:11 oxygenated. 136:12 Q. It's important for a 136:13 patients ability to live and to strive, 136:14 correct? 136:15 A. Correct. 136:16 Q. And when that vessel is	

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	136:17 placed in jeopardy, that means that the 136:18 patients at risk of having her health and 136:19 wellbeing jeopardized?	
136:22 - 137:7	**Moritz, Mark 07-18-2017 (00:00:25)** 136:22 THE WITNESS: Correct. 136:23 BY MR. O'CONNOR: 136:24 Q. And I think you would agree, 137:1 while you've talked about the use of 137:2 other types of devices and where they may 137:3 be inserted, certainly the Bard Eclipse 137:4 filter was never represented as a filter 137:5 that would fracture, break, and have a 137:6 piece embolize into the pulmonary artery, 137:7 correct?	05_01_18 Jones Combo V2.46
137:10 - 137:14	**Moritz, Mark 07-18-2017 (00:00:05)** 137:10 THE WITNESS: Correct. 137:11 BY MR. O'CONNOR: 137:12 Q. And that certainly is 137:13 contrary to the patient's reasonable 137:14 expectations, correct?	05_01_18 Jones Combo V2.47
137:17 - 137:17	**Moritz, Mark 07-18-2017 (00:00:00)** 137:17 THE WITNESS: Yes.	05_01_18 Jones Combo V2.48
138:24 - 139:9	**Moritz, Mark 07-18-2017 (00:00:22)** 138:24 Q. And in fairness to 139:1 Mrs. Jones, certainly you agree that 139:2 neither her doctors nor her should have 139:3 expected this complication to occur? 139:4 A. Correct. 139:5 Q. And that it is -- the 139:6 fracture -- the fragment is lodged and 139:7 embedded into her right pulmonary artery 139:8 in the middle lobe? 139:9 A. Yes, that's what it says.	05_01_18 Jones Combo V2.49
139:18 - 139:19	**Moritz, Mark 07-18-2017 (00:00:03)** 139:18 Q. Certainly it exposes her to 139:19 a risk of further complications?	05_01_18 Jones Combo V2.50
139:22 - 140:11	**Moritz, Mark 07-18-2017 (00:00:19)** 139:22 THE WITNESS: I agree with 139:23 that. 139:24 BY MR. O'CONNOR:	05_01_18 Jones Combo V2.51

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	140:1 Q. And, certainly, if she was 140:2 your patient, as her doctor, and I can 140:3 tell this about you, it's something that 140:4 you would certainly be concerned about 140:5 for your patient? 140:6 A. Correct. 140:7 Q. And your advice to a patient 140:8 like Doris who had that problem would be 140:9 we need to keep our eyes on that at the 140:10 very least? 140:11 A. I agree with that.	
141:4 - 141:15	**Moritz, Mark 07-18-2017 (00:00:25)** 141:4 Q. Well, that is a delicate 141:5 part of the anatomy, a blood vessel in 141:6 the pulmonary -- the pulmonary artery, 141:7 correct? 141:8 A. Correct. 141:9 Q. And certainly something that 141:10 makes the filter complication even more 141:11 complex and more complicated because of 141:12 where it's embedded? 141:13 A. More complicated than what? 141:14 Q. Than you would expect it to 141:15 be if it never failed.	05_01_18 Jones Combo V2 53
141:19 - 141:20	**Moritz, Mark 07-18-2017 (00:00:01)** 141:19 Q. True? 141:20 A. Yes.	05_01_18 Jones Combo V2 54
143:24 - 144:6	**Moritz, Mark 07-18-2017 (00:00:12)** 143:24 Q. I guess I was thinking of 144:1 something more in my mind as a layperson, 144:2 if it becomes further detached -- 144:3 detached and migrates further, that's 144:4 certainly something that you cannot rule 144:5 out, true? 144:6 A. Perhaps.	05_01_18 Jones Combo V2 55
144:15 - 145:3	**Moritz, Mark 07-18-2017 (00:00:16)** 144:15 Q. But certainly something that 144:16 you have to be concerned about as a 144:17 medical doctor? 144:18 A. Have to be concerned about	

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	144:19 it being there. 144:20 Q. You certainly encourage her 144:21 to continue to follow-up with her doctor 144:22 to monitor that, true? 144:23 A. I do. 144:24 Q. And you think she should go 145:1 to her doctor on a regular basis to have 145:2 it monitored, correct? 145:3 A. Correct.	
146:11 - 147:9	**Moritz, Mark 07-18-2017 (00:00:41)** 146:11 Q. setting aside whether 146:12 it's his logic, Doris Jones has got a 146:13 fractured filter in her pulmonary artery, 146:14 and I think you and I can leave here 146:15 today agreeing that's a bad thing 146:16 medically, fair? 146:17 146:18 146:19 THE WITNESS: Correct. 146:20 BY MR. O'CONNOR: 146:21 Q. And certainly we can agree 146:22 that Doris Jones deserves and is entitled 146:23 to every chance she can to be safe from 146:24 that fragment, correct? 147:1 A. Correct. 147:2 Q. And certainly something that 147:3 if she were your patient, you would agree 147:4 and that if you're consulted with a 147:5 doctor from another discipline, you would 147:6 be open to any suggestion that doctor had 147:7 to protect Doris Jones and give her every 147:8 opportunity, every chance to survive from 147:9 this failure that's exposing her to harm?	05_01_18 Jones Combo V2.56
147:12 - 147:16	**Moritz, Mark 07-18-2017 (00:00:05)** 147:12 THE WITNESS: I agree. 147:13 BY MR. O'CONNOR: 147:14 Q. And Doris Jones is exposed 147:15 to harm every day that fragment is with 147:16 her, true?	05_01_18 Jones Combo V2.57
147:19 - 148:5	**Moritz, Mark 07-18-2017 (00:00:06)**	05_01_18 Jones Combo V2.58

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	147:19 THE WITNESS: A very small 147:20 amount. 147:21 BY MR. O'CONNOR: 147:22 Q. But that can change at any 147:23 moment? 147:24 148:1 148:2 THE WITNESS: It can change. 148:3 BY MR. O'CONNOR: 148:4 Q. You agree with that? 148:5 A. Yes.	
149:3 - 149:14	**Moritz, Mark 07-18-2017 (00:00:23)** 149:3 Q. But certainly it caused 149:4 enough of a medical condition that it 149:5 warrants serious attention by doctors? 149:6 A. I agree. 149:7 Q. And if there was an 149:8 opportunity to remove it, that's what you 149:9 would recommend? 149:10 A. I would. 149:11 Q. Your concern is, is that 149:12 it's in such a position that it can't be 149:13 removed and how much more harm can you 149:14 expose this lady to?	05_01_18 Jones Combo V2.69
149:17 - 149:18	**Moritz, Mark 07-18-2017 (00:00:01)** 149:17 THE WITNESS: I think it's 149:18 removable.	05_01_18 Jones Combo V2.69

Plaintiffs Designations = 00:08:24
Defense Designations = 00:00:25
Total Time = 00:08:49

Exhibit J

Designation Run Report

Nelson 03-23-17 Jones Trial run V6

Nelson, Kirstin 03-23-2017

Plaintiffs Designations 00:15:02

Defense Designations 00:09:39

Plaintiffs and Defense Designations 00:09:47

Total Time 00:34:28

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12:4 - 12:19	Nelson, Kirstin 03-23-2017 (00:00:44)	05_21_18 Combo V6.2
	12:4 Do you have experience 12:5 with IVC filters? 12:6 A. I have placed many IVC filters and removed 12:7 many IVC filters. 12:8 Q. Okay. And how long have you had 12:9 experience in both implanting and removing filters? 12:10 A. As a solo operator for, you know, the 12:11 11 years, but also during that previous seven years, 12:12 during which I was in training in both radiology and 12:13 in fellowship, we also did IVC filter procedures. 12:14 Q. About how frequently -- and if there's a 12:15 difference in different points in time, let us 12:16 know -- but about how frequently do you implant IVC 12:17 filters in patients? 12:18 A. Things always vary, but I would say in 12:19 general, one to two times a week.	
12:20 - 13:7	Nelson, Kirstin 03-23-2017 (00:00:44)	05_21_18 Combo V6.3
	12:20 Q. And can you explain for the jury 12:21 the process of how you implant an IVC filter? 12:22 A. Sure. The first thing is patient 12:23 selection. You need -- typically, IVC filters are 12:24 placed to prevent an often fatal event called a 12:25 pulmonary embolism, where a blood clot -- typically 13:1 from within the pelvic or leg veins -- would break 13:2 off, travel through the bloodstream, and go to the 13:3 lungs and compromise the perfusion and oxygenation of 13:4 the patient and their body. 13:5 So there are often cases where patients 13:6 who have blood clots cannot receive a blood thinner, 13:7 which would typically be the treatment.	
19:8 - 19:16	Nelson, Kirstin 03-23-2017 (00:00:25)	05_21_18 Combo V6.4
	19:8 Q. Let me ask you a question and go back to 19:9 your involvement particularly in Mrs. Jones' case. 19:10 Do you -- sitting here today, do you recall 19:11 Mrs. Jones? 19:12 A. Vaguely. I do recall her case more than 19:13 her specifically. But, you know, I remember seeing 19:14 her in the emergency department and discussing things 19:15 with her and, you know, then performing her	

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	19:16 procedure.	
19:22 - 20:3	Nelson, Kirstin 03-23-2017 (00:00:19)	05_21_18 Combo V6.81
	19:22 Q. is it fair to say that you remember 19:23 Mrs. Jones in particular because of the facts and 19:24 circumstances surrounding her filter removal? 19:25 A. Yeah. You know, typically this is -- you 20:1 know, more of a scheduled kind of elective thing. 20:2 But, you know, it's not usual we see a patient in the 20:3 ER for a filter removal.	
20:10 - 20:13	Nelson, Kirstin 03-23-2017 (00:00:16)	05_21_18 Combo V6.5
	20:10 Q. So we have handed you -- which is a 20:11 document that's been marked as 4013, which is a copy 20:12 of the medical records for Mrs. Jones from the 20:13 Memorial Health University Center here in Savannah.	
20:16 - 20:23	Nelson, Kirstin 03-23-2017 (00:00:33)	05_21_18 Combo V6.6
	20:16 Q. And can you explain to the jury 20:17 what this is? 20:18 A. This is a history and physical, basically, 20:19 from the attending physician and resident who saw 20:20 Ms. Jones in the emergency room, and their summary of 20:21 why she was there and some of the findings that she 20:22 presented with, with her initial encounter, and their 20:23 plans to systematically address those issues.	
20:24 - 21:6	Nelson, Kirstin 03-23-2017 (00:00:20)	05_21_18 Combo V6.66
	20:24 Q. And if we see this, in this record, we see 20:25 that Mrs. Jones came into the emergency department 21:1 with complaints of lightheadedness and bilateral arm 21:2 pain. And then it -- later on in the record, it 21:3 indicates she had lightheadedness accompanied with 21:4 diaphoresis. Can you tell the jury what diaphoresis 21:5 is? 21:6 A. Sweating.	
21:7 - 21:16	Nelson, Kirstin 03-23-2017 (00:00:25)	05_21_18 Combo V6.8
	21:7 Q. And then in the last sentence 21:8 of this Exhibit 4013, it says that: 21:9 "A chest radiograph in the emergency 21:10 department did show a metallic object in the right 21:11 hilum, which was then better elucidated on CT 21:12 angiogram of the lungs which showed probable IVC 21:13 filter piece in the right middle lobe pulmonary	

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	21:14 artery."	
	21:15 Did I read that correctly?	
	21:16 A. Close enough.	
22:11 - 22:24	Nelson, Kirstin 03-23-2017 (00:00:42)	05_21_18 Combo V6.10
	22:11 Q. Can you tell the jury what the	
	22:12 right hilum is?	
	22:13 A. The right hilum --	
	22:14 Q. Hilum. There we go.	
	22:15 A. -- is kind of a -- it's a combination --	
	22:16 it's -- basically describes a structure that you	
	22:17 would see on -- on imaging, where the pulmonary	
	22:18 artery, the pulmonary vein and the right and left	
	22:19 main stem bronchi split off on either side. There's	
	22:20 a right side and a left side, so there's a right	
	22:21 hilum and a left hilum. And that's a shadow that you	
	22:22 would see on a chest x-ray. And you would see,	
	22:23 basically, on the chest x-ray, this metallic object	
	22:24 projecting over it.	
23:9 - 23:11	Nelson, Kirstin 03-23-2017 (00:00:06)	05_21_18 Combo V6.11
	23:9 Q. And it indicates here that subsequently	
	23:10 she had a CT angiogram of the lungs done, correct?	
	23:11 A. Correct.	
25:2 - 25:6	Nelson, Kirstin 03-23-2017 (00:00:06)	05_21_18 Combo V6.12
	25:2 Q. in this case, you did	
	25:3 not perform either the original x-ray or the CT?	
	25:4 A. No.	
	25:5 Q. Did you review those films at some point?	
	25:6 A. I did.	
25:7 - 25:17	Nelson, Kirstin 03-23-2017 (00:00:36)	05_21_18 Combo V6.13
	25:7 Q. And how did you, to the best of your	
	25:8 recollection, get involved in the care and treatment	
	25:9 of Mrs. Jones?	
	25:10 A. After it had been discovered that she had	
	25:11 a -- what was most likely a fragment of her IVC	
	25:12 filter in her pulmonary arteries, they had contacted	
	25:13 me to -- and I am unclear if this was the ER	
	25:14 physician, or it may have been the radiologist; I	
	25:15 don't remember quite far that back -- to see	
	25:16 initially about removing that piece of the filter	
	25:17 which had embolized to the pulmonary artery.	

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25:25 - 26:3	Nelson, Kirstin 03-23-2017 (00:00:11) 25:25 Q. Let me ask you if you would turn to page 3 26:1 of the exhibit. And it has there, towards the 26:2 bottom, something that's indicated as an assessment 26:3 and plan.	05_21_18 Combo V6.16
26:22 - 27:1	Nelson, Kirstin 03-23-2017 (00:00:11) 26:22 Q. So the next thing we see, it says: 26:23 "Patient to angio suite with interventional radiology 26:24 for IVC filter removal tomorrow." 26:25 Under "A." Do you see that? 27:1 A. Yes.	05_21_18 Combo V6.17
27:2 - 27:5	Nelson, Kirstin 03-23-2017 (00:00:09) 27:2 Q. And is that a reference to you? 27:3 A. That probably was. At this point, it -- 27:4 for that portion of it, they did discuss that with 27:5 me.	05_21_18 Combo V6.18
27:6 - 27:11	Nelson, Kirstin 03-23-2017 (00:00:16) 27:6 Q. And the IVC filter removal is 27:7 referring to what? 27:8 A. The actual -- not the fragment of the IVC, 27:9 which was in the pulmonary artery, but the filter 27:10 itself, which was still within the inferior vena 27:11 cava.	05_21_18 Combo V6.19
27:12 - 28:1	Nelson, Kirstin 03-23-2017 (00:00:41) 27:12 Q. at this point, in terms of what we have 27:13 is you have the filter, which is at or near its 27:14 original point of implant, and the piece of it that's 27:15 broken off, and we use the term "migrated," but moved 27:16 through the body up into a different position. 27:17 Correct? 27:18 A. That's correct. 27:19 Q. And in terms of the path that we're 27:20 talking about here, the piece that broke off, 27:21 assuming it started from the filter itself, how did 27:22 that travel and where did it end up? 27:23 A. So it traveled, you know, from the 27:24 inferior vena cava through the chambers of the heart 27:25 to the pulmonary outflow tract, and then into the 28:1 right middle lobe pulmonary artery.	05_21_18 Combo V6.20
28:25 - 29:12	Nelson, Kirstin 03-23-2017 (00:00:37)	05_21_18 Combo V6.21

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	28:25 Q. So in this case, the filter fragment after 29:1 it broke -- I'm going to -- "float" is probably the 29:2 wrong word, but got pushed and moved up through -- 29:3 A. With the flow of blood. 29:4 Q. -- with the flow of blood, through the two 29:5 chambers of Mrs. Jones' heart, and into that 29:6 pulmonary artery that's traveling to the lungs, and 29:7 then got caught there in or about where it meets up 29:8 with the lung; is that right? 29:9 A. Yeah. It basically -- if something is 29:10 going to embolize, it's going to travel with the flow 29:11 of blood and then lodge at the smallest or narrowest 29:12 point where it can get through.	
29:13 - 29:17	Nelson, Kirstin 03-23-2017 (00:00:08) 29:13 Q. And in this one, it ended up not in the 29:14 lungs but just outside the lungs, in the pulmonary 29:15 artery? 29:16 A. Right. This is not in the lung 29:17 parenchyma, like people would think of the lungs.	05_21_18 Combo V6.22
29:18 - 29:20	Nelson, Kirstin 03-23-2017 (00:00:03) 29:18 Q. You just used a word that I don't 29:19 understand. 29:20 A. Lung tissue.	05_21_18 Combo V6.23
30:9 - 30:14	Nelson, Kirstin 03-23-2017 (00:00:17) 30:9 Q. So is it your understanding, by the time 30:10 you were even contacted, that the original treating 30:11 doctors thought that the fractured and fragmented 30:12 piece that had traveled up through the heart and into 30:13 the lungs shouldn't be removed? 30:14 A. Yes.	05_21_18 Combo V6.62
30:15 - 31:1	Nelson, Kirstin 03-23-2017 (00:00:44) 30:15 Q. And did they consult with you at any point 30:16 about that? 30:17 A. Yes. I said that there would be more 30:18 danger and more risk in removing that small fragment, 30:19 which is -- you know, just like a very thin wire, 30:20 maybe a centimeter and a half in length -- to try to 30:21 fish that out, than there would be in just leaving it 30:22 where it was, because it was such a small -- a small 30:23 piece. It wasn't going to go any place. It had	05_21_18 Combo V6.24

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	30:24 already lodged at that furthest point. And it had 30:25 been there probably for quite some time without 31:1 causing any ill effect.	
31:2 - 31:12	Nelson, Kirstin 03-23-2017 (00:00:45) 31:2 Q. well, let's talk for a minute 31:3 about -- and we will come back to this, but there's a 31:4 reference in the records to a comparison between a 31:5 couple of different films. Do you recall that? 31:6 A. Yes. I -- before I had performed 31:7 Mrs. Jones' filter removal, I had gone back and 31:8 looked at her x-rays which had been performed at 31:9 Memorial. And sometime -- I believe it was 2013 -- 31:10 there was not a fragment there, and sometime between 31:11 2013 and 2015, at least by imaging, that's when that 31:12 filter limb had broken off.	05_21_18 Combo V6.25
31:17 - 31:18	Nelson, Kirstin 03-23-2017 (00:00:05) 31:17 Q. The court reporter has handed you what's 31:18 been marked as Exhibit 4014	05_21_18 Combo V6.26
31:24 - 32:1	Nelson, Kirstin 03-23-2017 (00:00:09) 31:24 Q. What is this document? 31:25 A. This is the report by the reading 32:1 radiologist of Mrs. Jones' initial chest x-ray.	05_21_18 Combo V6.27
32:21 - 33:14	Nelson, Kirstin 03-23-2017 (00:00:39) 32:21 Dr. Britt indicates here that he -- in the 32:22 impression -- well, first it says "Comparison, 32:23 April 21, 2015, to August 14, 2013." 32:24 Do you see that? 32:25 A. Yes. 33:1 Q. And that's consistent with what you just 33:2 said, which was that there was an image from sometime 33:3 in 2013 -- 33:4 A. Uh-huh. 33:5 Q. -- that you looked at. And in your review 33:6 of the -- you reviewed both films, correct? 33:7 A. Correct. 33:8 Q. And in your review of that earlier film, 33:9 the filter was intact? 33:10 A. You did not see that radiopaque density on 33:11 the chest x-ray in the 2013 image. 33:12 Q. You just said "radiopaque density"; what	05_21_18 Combo V6.28

Page/Line	Source	ID
	33:13 do you mean?	
	33:14 A. You do not see the filter limb.	
33:21 - 34:16	**Nelson, Kirstin 03-23-2017 (00:00:48)**	05_21_18 Combo V6.30
	33:21 Q. And his review here is consistent with 33:22 what you saw when you looked at those films; is that 33:23 correct? 33:24 A. Yes. 33:25 Q. But you did your own separate review of 34:1 those to make sure that you understood what was going 34:2 on, correct? 34:3 A. Right. I don't issue a separate report. 34:4 I'm not really interpreting those; I'm just looking 34:5 at the imaging to guide my decision-making process. 34:6 Q. And likewise, you looked at the images 34:7 from the CT that were taken at the time? 34:8 A. Yes. 34:9 Q. And what information did those convey to 34:10 you? 34:11 A. Pretty much what we had discussed, that -- 34:12 I don't know if you need another exhibit number or 34:13 whatever for the CT report, but basically that this 34:14 did appear to be a limb from the filter which was 34:15 within the right middle lobe pulmonary artery at a 34:16 distal point which was not flow limiting.	
34:17 - 34:22	**Nelson, Kirstin 03-23-2017 (00:00:15)**	05_21_18 Combo V6.31
	34:17 Q. you looked at both of 34:18 those images, scans, and had a consistent 34:19 determination that you needed to remove the filter; 34:20 is that correct? 34:21 A. The filter itself, but not the fragment 34:22 within the pulmonary artery.	
34:23 - 35:19	**Nelson, Kirstin 03-23-2017 (00:01:01)**	05_21_18 Combo V6.32
	34:23 Q. Let me ask you this question: At 34:24 that point in time, in April of 2015, why did the 34:25 filter itself need to come out? 35:1 A. Because now that it has a strut or a limb 35:2 or a leg, whatever you want to call it, missing, 35:3 there was concern that the integrity of the filter 35:4 was compromised, and there would be a risk of another 35:5 limb potentially breaking off or the filter itself	

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	35:6 potentially migrating. 35:7 Q. Okay. And what are the possible results 35:8 of those things happening? 35:9 A. You know, you could have exactly the same 35:10 thing happen here, where it would just go to a 35:11 pulmonary artery. Where you worry about, is the limb 35:12 or the filter going to the heart and causing an issue 35:13 there? 35:14 Q. Okay. And -- and so your recommendation 35:15 at the time was to go in, as you've discussed 35:16 before -- and we will get into the details of how it 35:17 happens -- but to go in and actually retrieve the 35:18 filter. Correct? 35:19 A. Yes.	
35:20 - 36:10	Nelson, Kirstin 03-23-2017 (00:00:52) 35:20 Q. Let me ask you to turn back to the first 35:21 exhibit, which is 4013, and we were talking about 35:22 page 3. But let me ask you if you turn over to 35:23 page 4. 35:24 A. Okay. 35:25 Q. And these are more of the assessment and 36:1 plan notes made by the attending physician. But if 36:2 we go down to items -- item number 6, it says: 36:3 "There is a history of deep venous thrombosis status 36:4 post inferior vena cava filter placement." 36:5 What does that mean? 36:6 A. Okay. So it means that she had a blood 36:7 clot within a deep vein, presumably one of the pelvic 36:8 or leg veins, that was apparently, they thought, the 36:9 result of her being somewhat incapacitated from prior 36:10 surgery.	05_21_18 Combo V6.33
37:12 - 37:18	Nelson, Kirstin 03-23-2017 (00:00:13) 37:12 Q. So the court reporter had handed you what 37:13 has been marked as Exhibit 4015 to this deposition, 37:14 which I believe is your operative report. Is that 37:15 correct? 37:16 A. Yes. 37:17 Q. And it has the date of April 23, 2015, at 37:18 the top.	05_21_18 Combo V6.34
38:18 - 38:20	Nelson, Kirstin 03-23-2017 (00:00:04)	05_21_18 Combo V6.35

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	38:18 Q. Let me ask you to 38:19 turn to the third page of the document, which appears 38:20 to be notes	
39:13 - 40:4	Nelson, Kirstin 03-23-2017 (00:01:01) 39:13 Q. Can you walk us briefly through your notes 39:14 here and what they mean? 39:15 A. Sure. My preop diagnosis was what I 39:16 abbreviated, fractured filter. It says "FX'd 39:17 filter." My post-op diagnosis was "Same." My 39:18 procedure was an inferior vena cavagram and filter 39:19 retrieval. The medication that I gave for this were 39:20 two drugs called Versed and fentanyl, for sedation of 39:21 the patient while we did the procedure. The surgeon 39:22 was myself; I had no assistants. 39:23 And my description of my findings was that 39:24 the IVC itself appeared intact, and that when the 39:25 filter was removed, it did look like one of the 40:1 shorter struts on the filter itself was the fractured 40:2 portion. There were no complications. Specimens 40:3 which were removed were the IVC filter. And blood 40:4 loss was essentially none.	05_21_18 Combo V6.36
45:10 - 45:18	Nelson, Kirstin 03-23-2017 (00:00:31) 45:10 Q. did you 45:11 discuss with Mrs. Jones, any potential benefits of 45:12 leaving the broken filter in? 45:13 A. Basically the only real benefit of leaving 45:14 the filter in would be to avoid a procedure to take 45:15 it out. And her filter had been in for five years or 45:16 so, give or take, at this point. And sometimes 45:17 there's more risks associated with taking a filter 45:18 which has been indwelling for that time period out.	05_21_18 Combo V6.38
45:19 - 46:12	Nelson, Kirstin 03-23-2017 (00:01:01) 45:19 Q. let me ask this: Because of the 45:20 fact that it was broken, did that potentially affect 45:21 the -- if it had stayed in, aside from the risk that 45:22 you identified of it breaking, independent of that, 45:23 does the fact that it was broken and missing one of 45:24 the struts potentially affect the efficacy of the 45:25 device? 46:1 A. It was a very small, shorter strut. I	05_21_18 Combo V6.39

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	46:2 mean, I think it still would have served its purpose, 46:3 to catch a significant pulmonary embolism. But, you 46:4 know, I think that she was no longer in that 46:5 perioperative time period, and they had also -- I 46:6 don't know if I'm getting ahead of myself here -- had 46:7 done an ultrasound of her legs to make sure that 46:8 there were no more residual blood clots that would be 46:9 a risk for embolization. 46:10 Q. Okay. In other words, at the time, you 46:11 weren't worried about a clot coming through? 46:12 A. Correct.	
46:19 - 47:1	Nelson, Kirstin 03-23-2017 (00:00:32) 46:19 Q. And did you discuss with her the 46:20 possibility of doing a procedure to remove the 46:21 fractured part? 46:22 A. I had advised against doing that removal 46:23 of the fractured part. It was such a small piece, 46:24 and where it was would be a little bit of effort, but 46:25 not impossible to get to. But, you know, could -- 47:1 could carry a little bit more risk with it.	05_21_18 Combo V6.60
47:17 - 47:21	Nelson, Kirstin 03-23-2017 (00:00:09) 47:17 You advised the client, the patient, 47:18 Mrs. Jones, that the risk of removal was, you 47:19 thought, greater than necessary to go through the 47:20 procedure of taking out that piece? 47:21 A. Yes.	05_21_18 Combo V6.62
47:25 - 48:9	Nelson, Kirstin 03-23-2017 (00:00:31) 47:25 Q. After 48:1 you've done that, what do you do in terms of the 48:2 procedure to remove the filter? 48:3 A. So the -- you know, patient is taken to 48:4 the angiography suite, which is where we have that 48:5 continuous fluoroscopic device that I had described. 48:6 And the patient is typically given, through a 48:7 peripheral IV, some sedation -- in this case, Versed 48:8 and fentanyl -- to make the whole thing a little bit 48:9 easier on them.	05_21_18 Combo V6.63
48:10 - 49:2	Nelson, Kirstin 03-23-2017 (00:01:04) 48:10 Following sedation, we prep the area, 48:11 which in this case would be the right jugular vein,	05_21_18 Combo V6.64

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	48:12 with, you know, antiseptic soap, and drape everything 48:13 so there's just a small area exposed that we would be 48:14 looking through, to minimize any potential risk of 48:15 infection. And then under ultrasound, we would gain 48:16 access into the jugular vein with a small needle, and 48:17 then place a small wire into that vein. And then 48:18 over that put a small sheath that we can then work 48:19 through and put our wire that we're going to use, 48:20 which is slightly thicker wire, and navigate that 48:21 into the inferior vena cava. 48:22 And once we have that working wire, as we 48:23 call it, in place, then we're able to put a sheath 48:24 in, which is a slightly thicker, hollow tube. 48:25 Through that we can take our pictures, which we did, 49:1 and did an inferior -- what they call an inferior 49:2 vena cavagram, where we would inject x-ray dye into	
49:2 - 49:11	**Nelson, Kirstin 03-23-2017 (00:00:27)** 49:2 where we would inject x-ray dye into 49:3 that vein in the belly where the filter sits. We do 49:4 that to make sure that the filter doesn't have a 49:5 large amount of clot within -- within it that we 49:6 could potentially dislodge, if we take the filter 49:7 itself out. Her filter looked clean and not full of 49:8 thrombus. So then -- 49:9 Q. Let me stop you for just a second, if you 49:10 don't mind. 49:11 A. Okay.	05_21_18 Combo V6.46
49:12 - 50:11	**Nelson, Kirstin 03-23-2017 (00:00:45)** 49:12 Q. when you initially put the first wire 49:13 in and you run it through, you come into the jugular, 49:14 near the -- up in the neck? 49:15 A. Uh-huh. 49:16 Q. And you insert a wire that travels down 49:17 through the jugular, through the heart, into the IVC? 49:18 A. Correct. 49:19 Q. And then over that, you pass a sheath? 49:20 A. Right. 49:21 Q. And through that sheath, you inject some 49:22 dye or contrast, as you've described before, so that 49:23 you can see on the imaging where the -- where the	05_21_18 Combo V6.46

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	49:24 vein is and what's going on in there; is that 49:25 correct? 50:1 A. That's correct. 50:2 Q. Okay. And then as part of that you said 50:3 you do an angiogram to see if there's any clotting or 50:4 anything in the filter. Yes? 50:5 A. That's where -- yeah, that is that 50:6 venogram -- 50:7 Q. Right. 50:8 A. -- that we're doing to see where it's 50:9 sitting, to see, you know, that the clot -- that 50:10 there is not clot within the filter before we take it 50:11 out.	
51:1 - 51:17	Nelson, Kirstin 03-23-2017 (00:00:48) 51:1 Q. What do you do after you've 51:2 determined that that area is clear? 51:3 A. So if the patient -- if that area is clear 51:4 and it looks like the patient can have their filter 51:5 removed, we put basically a snare, or kind of a 51:6 lasso, in through that sheath to grasp the very apex 51:7 of the filter, which has a little hook on it. After 51:8 we grasp that little hook to kind of steady the 51:9 filter, we advance that sheath that we're working 51:10 through to recollapse the filter, kind of in the 51:11 reverse way of how we put it in. 51:12 Q. Closing the umbrella? 51:13 A. Closing the umbrella. So once we close 51:14 the umbrella and have it within the sheath, we just 51:15 take everything out of the patient. 51:16 Q. And that's what you did here? 51:17 A. Yes.	05_21_18 Combo V5.47
51:18 - 51:21	Nelson, Kirstin 03-23-2017 (00:00:05) 51:18 Q. And when you take it out of the patient, 51:19 you're running it back over the wire, through the 51:20 heart, and out through the jugular, correct? 51:21 A. Yes.	05_21_18 Combo V6.48
55:1 - 55:12	Nelson, Kirstin 03-23-2017 (00:00:38) 55:1 Q. And what did you do next? 55:2 A. So after we did that venogram, the 55:3 retrieval device was put through that sheath and used	05_21_18 Combo V6.49

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	55:4 to grasp that top hook or the apex of the filter.	
	55:5 And then the filter is basically collapsed, like	
	55:6 you're closing the umbrella again, and withdrawn from	
	55:7 the patient.	
	55:8 Q. Okay. And after -- after you do all	
	55:9 that -- well, let's -- let me -- says: "Inspection	
	55:10 of the filter reveals fracture one of the six shorter	
	55:11 struts circumferentially around the filter." Is that	
	55:12 right?	
55:15 - 55:19	Nelson, Kirstin 03-23-2017 (00:00:09)	05_21_18 Combo V6.60
	55:15 A. Yes.	
	55:16 Q. And that's a reference to the filter --	
	55:17 you inspected the filter and found that one of the	
	55:18 arms had been broken off?	
	55:19 A. Right. One of the shorter arms. There	
55:19 - 55:21	Nelson, Kirstin 03-23-2017 (00:00:06)	05_21_18 Combo V6.61
	55:19 A. Right. One of the shorter arms. There	
	55:20 were longer -- longer arms and shorter arms, and it	
	55:21 was one of the shorter arms which had broken off.	
55:22 - 56:16	Nelson, Kirstin 03-23-2017 (00:00:51)	05_21_18 Combo V6.62
	55:22 Q. Did you have any further kind of --	
	55:23 I assume that you pulled out the devices and the	
	55:24 wires and all that stuff at that point, correct?	
	55:25 A. Right. And then, before I -- before I	
	56:1 actually pulled them out, though, I also did a	
	56:2 followup inferior vena cavagram. So after I pulled	
	56:3 the filter out, I still have the sheath in. So I	
	56:4 shot more x-ray dye through there, to make sure that	
	56:5 the IVC itself wasn't injured in removal of the	
	56:6 filter.	
	56:7 Q. And what did you find?	
	56:8 A. That it was fine.	
	56:9 Q. And then after you take everything out, do	
	56:10 you -- did you do anything further with this patient	
	56:11 at that time?	
	56:12 A. No, basically it's -- this is all done	
	56:13 through a small nick in the skin that's only a few	
	56:14 millimeters in size. We take the device out. We do	
	56:15 our workthrough, hold pressure for five minutes over	
	56:16 the puncture site, and put a Band-Aid on it.	

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60:3 - 60:7	Nelson, Kirstin 03-23-2017 (00:00:15) 60:3 Q. The court reporter has handed you 60:4 what has been marked as the next exhibit in this 60:5 proceeding, which is 4017, which is the operative 60:6 report from August 24th, 2010, of Dr. Avino for the 60:7 placement of this filter.	05_21_18 Combo V6:53
60:17 - 61:2	Nelson, Kirstin 03-23-2017 (00:00:18) 60:17 Q. Let me ask you this question: At the end 60:18 of the first paragraph, under "Indications," that's 60:19 where it -- was the language I was reading before, 60:20 which says: "After a long discussion with the 60:21 patient, she opted for a retrievable filter, 60:22 suspecting this would likely remain permanent." 60:23 Do you see that? 60:24 A. Yes, I do. 60:25 Q. And if you reviewed this record at the 61:1 time, that's something you would have seen, correct? 61:2 A. Uh-huh.	05_21_18 Combo V6:55
61:11 - 61:14	Nelson, Kirstin 03-23-2017 (00:00:11) 61:11 Q. Was it your understanding at the 61:12 time that it was marketed by the manufacturer, by 61:13 Bard, as appropriate for a permanent filter? 61:14 A. To the best of my recollection.	05_21_18 Combo V6:03
62:5 - 62:9	Nelson, Kirstin 03-23-2017 (00:00:16) 62:5 Do you recall that during this time 62:6 period in 2010, that Bard was marketing the Eclipse 62:7 filter as being safe to stay in the body of a patient 62:8 as a permanent filter, even though it had a 62:9 retrievable indication?	05_21_18 Combo V6:06
62:11 - 62:12	Nelson, Kirstin 03-23-2017 (00:00:03) 62:11 THE WITNESS: As far as I would -- 62:12 yes.	05_21_18 Combo V6:07
63:21 - 64:5	Nelson, Kirstin 03-23-2017 (00:00:41) 63:21 I think you indicated that at 63:22 some point in time, that your practice has -- or the 63:23 hospital has only been implanting retrievable 63:24 devices; is that correct? 63:25 A. I think that's the general -- general 64:1 consensus, that -- I'm not sure exactly when that 64:2 began, but I think unless there's a reason to -- to	05_21_18 Combo V6:09

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	64:3 not, you know, I think it leaves the door open to 64:4 potentially, you know, removing the filter if you 64:5 should have a case to do that in the future.	
65:2 - 65:10	Nelson, Kirstin 03-23-2017 (00:00:28) 65:2 Q. Do you recall receiving any information 65:3 from -- from Bard, during that period of time that 65:4 you started in 2006, comparative information and 65:5 comparative risk analysis between its -- its 65:6 retrievable filters that it was marketing and selling 65:7 at the time, and its permanent device that it -- for 65:8 at least a period of that time, the Simon Nitinol 65:9 filter, that it was also marketing at that time? 65:10 A. I don't recall.	05_21_18 Combo V6.59
65:11 - 65:14	Nelson, Kirstin 03-23-2017 (00:00:14) 65:11 Q. Do you recall 65:12 receiving any kind of risk -- comparative risk 65:13 information from Bard relating to any of its filters? 65:14 A. I don't,	05_21_18 Combo V6.60
67:25 - 69:5	Nelson, Kirstin 03-23-2017 (00:01:55) 67:25 Q. Will you look at the records in front of 68:1 you for the date that she came into the ER? Which 68:2 should be 4013. Do you see that? 68:3 A. Looks like date of admission is 4-22-2015. 68:4 Q. Yes. 68:5 A. Yes. 68:6 Q. And under the History, they've noted 68:7 symptoms that apparently she was subjectively 68:8 explaining to them; is that right? The 68:9 lightheadedness, bilateral arm pain? 68:10 A. Correct. My understanding, this would be 68:11 what brought her to the emergency department. 68:12 Q. Okay. And then down below, it says, "She 68:13 denies any chest pain, shortness of breath, back 68:14 pain, abdominal pain," and so on. Correct? 68:15 A. Yes. 68:16 Q. Did you make any determination with 68:17 respect to Ms. Jones that any of the symptoms that 68:18 she described when she came to the emergency room 68:19 were related in any way to her fractured filter 68:20 fragment?	05_21_18 Combo V6.61

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	68:21 A. I thought most likely that this was an 68:22 incidental finding on a chest x-ray. 68:23 Q. Meaning that you did not think that the 68:24 symptoms that she presented with at the ER were 68:25 related to the filter fragment? 69:1 A. (Moving head from side to side.) Correct. 69:2 Q. All right. Did you also not believe that 69:3 the body of her filter that she had in place was 69:4 causing any of those symptoms at that time? 69:5 A. Correct.	
69:21 - 70:10	Nelson, Kirstin 03-23-2017 (00:00:42) 69:21 Q. So you were able to look at that imaging, 69:22 the CT imaging, and see more than the chest x-ray. 69:23 True? 69:24 A. Correct. 69:25 Q. And from that more 3D imaging, you were 70:1 able to see that the -- that the fragment of the 70:2 filter was not flow limiting. Am I right? 70:3 A. Yes. 70:4 Q. And would you tell the jury what that 70:5 means, not flow limiting? 70:6 A. It means that the blood vessel in which it 70:7 had lodged still had blood flow around it, that it 70:8 wasn't acting like a -- a plug, basically, to occlude 70:9 or close off that branch, which you would not expect 70:10 it to anyways, due to its very small size.	05_21_18 Combo V6:62
70:11 - 70:23	Nelson, Kirstin 03-23-2017 (00:00:35) 70:11 Q. Were you able to determine how the 70:12 filter came to be fractured? 70:13 A. No. 70:14 Q. And you've already told us what you do 70:15 know is that it wasn't fractured by -- when you 70:16 looked at CTs, imaging of it in August of 2013? 70:17 A. Chest x-ray that was in 2013. 70:18 Q. So it happened sometime thereafter? 70:19 A. Right. 70:20 Q. And were you aware, at the time that you 70:21 retrieved the filter from Ms. Jones, that it had been 70:22 implanted in her for close to five years? 70:23 A. Yes.	05_21_18 Combo V6:63

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71:15 - 71:21	Nelson, Kirstin 03-23-2017 (00:00:11)	05_21_18 Combo V6.84
	71:15 Q. when you observed it, it was not in 71:16 the condition that it was when it was initially 71:17 placed, when it was complete. True? 71:18 A. Correct. 71:19 Q. Which caused you to recommend to her that 71:20 the filter should come out? 71:21 A. Yes.	
72:15 - 72:24	Nelson, Kirstin 03-23-2017 (00:00:21)	05_21_18 Combo V6.85
	72:15 Q. Did you believe that the retained 72:16 portion of the filter was causing Ms. Jones any 72:17 symptoms? 72:18 A. The one that was in the pulmonary artery? 72:19 Q. Yes. 72:20 A. No. 72:21 Q. And I think your testimony was that you 72:22 did not believe that it would cause her symptoms in 72:23 the future, either. True? 72:24 A. Correct.	
73:19 - 74:14	Nelson, Kirstin 03-23-2017 (00:00:58)	05_21_18 Combo V6.86
	73:19 Q. Was that retrieval procedure 73:20 that you went through any different from the typical 73:21 method that you use to retrieve an Eclipse filter? 73:22 A. No. 73:23 Q. So there was nothing about the 73:24 fractured -- the one fracture from the filter that 73:25 caused you to alter your procedure in that retrieval 74:1 for Mrs. Jones; is that correct? 74:2 A. Correct. I was concerned primarily about 74:3 the length of time that the filter had been in and 74:4 the ease with which I could get it out without 74:5 damaging the inferior vena cava. 74:6 Q. Okay. And it seems from your report and 74:7 your discussing the report with us that you were able 74:8 to successfully retrieve it without difficulty? 74:9 A. Correct. I didn't have to use any 74:10 above-and-beyond measures that we sometimes have to 74:11 do. 74:12 Q. And then without any injury to her, as 74:13 well, correct?	

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	74:14 A. Right.	
75:18 - 75:23	Nelson, Kirstin 03-23-2017 (00:00:15)	05_21_18 Combo V6.57
	75:18 Q. Mrs. Daly asked you some questions about 75:19 the term you used, "not flow limiting," and you 75:20 explained that you meant it's not occluding the vein 75:21 or stopping the flow of blood through the pulmonary 75:22 artery; is that correct? 75:23 A. Correct.	
76:16 - 76:20	Nelson, Kirstin 03-23-2017 (00:00:09)	05_21_18 Combo V6.58
	76:16 sort of in the same way that if there's an IVC filter 76:17 in the bloodstream, it is affecting, even if it's to 76:18 a minimal degree, it's affecting the flow of blood. 76:19 Correct? 76:20 A. Sure.	
76:24 - 77:4	Nelson, Kirstin 03-23-2017 (00:00:09)	05_21_18 Combo V6.59
	76:24 Q. And it could have similar effects in 76:25 whatever that does in terms of affecting the flow of 77:1 the blood, correct? 77:2 A. In that very small branch. 77:3 Q. Yes. 77:4 A. That's correct.	
77:13 - 78:6	Nelson, Kirstin 03-23-2017 (00:00:59)	05_21_18 Combo V6.60
	77:13 Is the reason that you recommended 77:14 the removal of the filter in this case because there 77:15 was a fracture? 77:16 A. Yes. 77:17 Q. And it -- can you explain in particular 77:18 why that fracture raised concerns for you, such that 77:19 you recommended removal? 77:20 A. If one of the stents has fractured, or one 77:21 of the struts of the filter had fractured, I felt 77:22 that there would be an increased risk of an 77:23 additional strut potentially fracturing in the future 77:24 and causing issues with that. So I suggested that we 77:25 would remove her filter and -- you know, if she 78:1 needed to have another filter replaced at some point 78:2 in the future, we could do that then. 78:3 Q. And that -- that advice and 78:4 recommendation, was it based on your training and 78:5 experience as an interventional radiologist?	

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	78:6 A. Yes.	
79:1 - 79:8	Nelson, Kirstin 03-23-2017 (00:00:25)	05_21_18 Combo V6.71
	79:1 Let me ask you a couple questions about the patient's 79:2 rights and reasonable expectations. 79:3 Would you agree with me that if Ms. -- 79:4 Mrs. Jones was told, at the time that this device was 79:5 implanted, that she could have it as a permanent 79:6 device, that it would be reasonable for her to expect 79:7 the device to remain in her body as a permanent 79:8 device?	
79:11 - 79:23	Nelson, Kirstin 03-23-2017 (00:00:22)	05_21_18 Combo V6.72
	79:11 THE WITNESS: Yes, if she was told that, 79:12 but I did not talk to her about that portion. 79:13 BY MR. STOLLER: 79:14 Q. Understood. But we saw the operative 79:15 report from Dr. Avino's implantation indicating that 79:16 it likely would remain as a permanent device. Do you 79:17 recall seeing that? 79:18 A. Yes, I do. 79:19 Q. And if that happened, would it be 79:20 reasonable for Mrs. Jones to expect that she would 79:21 have this remain as a permanent device? 79:22 *** 79:23 THE WITNESS: Yes.	
79:25 - 80:2	Nelson, Kirstin 03-23-2017 (00:00:09)	05_21_18 Combo V6.73
	79:25 Q. Would it be reasonable for her to expect 80:1 that the device that is implanted in her would remain 80:2 intact and not fracture?	
80:4 - 80:8	Nelson, Kirstin 03-23-2017 (00:00:09)	05_21_18 Combo V6.74
	80:4 THE WITNESS: I would imagine, yes. 80:5 BY MR. STOLLER: 80:6 Q. I mean, certainly it would be reasonable 80:7 for her to have an expectation that the device 80:8 wouldn't break; would you agree with that?	
80:10 - 80:14	Nelson, Kirstin 03-23-2017 (00:00:08)	05_21_18 Combo V6.76
	80:10 THE WITNESS: Yes. 80:11 BY MR. STOLLER: 80:12 Q. And in terms of to the extent if she had 80:13 that expectation, what she got instead was a device 80:14 that broke in her body. Correct?	

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80:16 - 80:16	Nelson, Kirstin 03-23-2017 (00:00:01)	05_21_18 Combo V6.78
	80:16 THE WITNESS: A part did break.	
81:24 - 82:3	Nelson, Kirstin 03-23-2017 (00:00:14)	05_21_18 Combo V6.79
	81:24 Q. Did you have an understanding from 81:25 your review of the medical records about anything 82:1 about Mrs. Jones' preexisting medical conditions? 82:2 A. It seemed like she had a fairly -- fairly 82:3 complex past medical history.	
82:10 - 83:3	Nelson, Kirstin 03-23-2017 (00:01:00)	05_21_18 Combo V6.84
	82:10 Q. Would you agree with me that the fact that 82:11 she had a more -- relatively complicated medical 82:12 history would leave her -- make it more risky for her 82:13 to undergo any kind of an interventional or operative 82:14 procedure? And by "more risky," I mean than the 82:15 average citizen, than the average person off the 82:16 streets. 82:17 A. I mean, probably more so than it would be 82:18 for a 18-year-old healthy person, you know, of 82:19 course. But, you know -- and we're talking about 82:20 interventional procedures versus operative 82:21 procedures, and they're pretty significantly 82:22 different in their risk profile. 82:23 Q. Okay. But for a -- for a person or a 82:24 patient such as Mrs. Jones, who's got a significant 82:25 medical history and gone through a number of 83:1 procedures in the past -- 83:2 A. Certainly if you can avoid doing 83:3 additional procedure on anybody, that is preferable.	
83:9 - 83:12	Nelson, Kirstin 03-23-2017 (00:00:10)	05_21_18 Combo V6.89
	83:9 Q. Do you think that Ms. Jones will have any 83:10 issues with blood flow in her body in the future, due 83:11 to this small fragment that's placed there? 83:12 A. No.	
83:15 - 83:24	Nelson, Kirstin 03-23-2017 (00:00:27)	05_21_18 Combo V6.90
	83:15 Q. When you -- when you treated Ms. Jones, 83:16 did you recommend to her that a new filter be placed? 83:17 A. No. 83:18 Q. And was that because you did not think she 83:19 needed the device at that time? 83:20 A. Yes.	

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83:21 Q. And bottom line is she had her filter
83:22 successfully removed by you without complication.
83:23 True?
83:24 A. True.

Plaintiffs Designations = 00:15:02
Defense Designations = 00:09:39
Plaintiffs and Defense Designations = 00:09:47
Total Time = 00:34:28